ResMed

Sleep Lab Titration Guide

S9™ Series
More. Comfort.

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Introduction

S9 VPAP™ Tx Lab System

ResMed's award-winning sleep lab titration system is designed with the patient's comfort in mind. A truly all-in-one lab system, the S9 VPAP™ Tx delivers comfortable therapy and caters to all patient types, allowing them to fall asleep and stay asleep, so your titrations are an overnight success.

The S9 VPAP Tx provides continuous positive airway pressure (CPAP) and bilevel therapy.

The S9 VPAP Tx is a component of the S9 VPAP Tx Lab System. The S9 VPAP Tx Lab System provides remote PC control of a positive airway pressure therapy device (therapy device) capable of delivering multiple therapy modes. The system comprises:

EasyCare Tx software

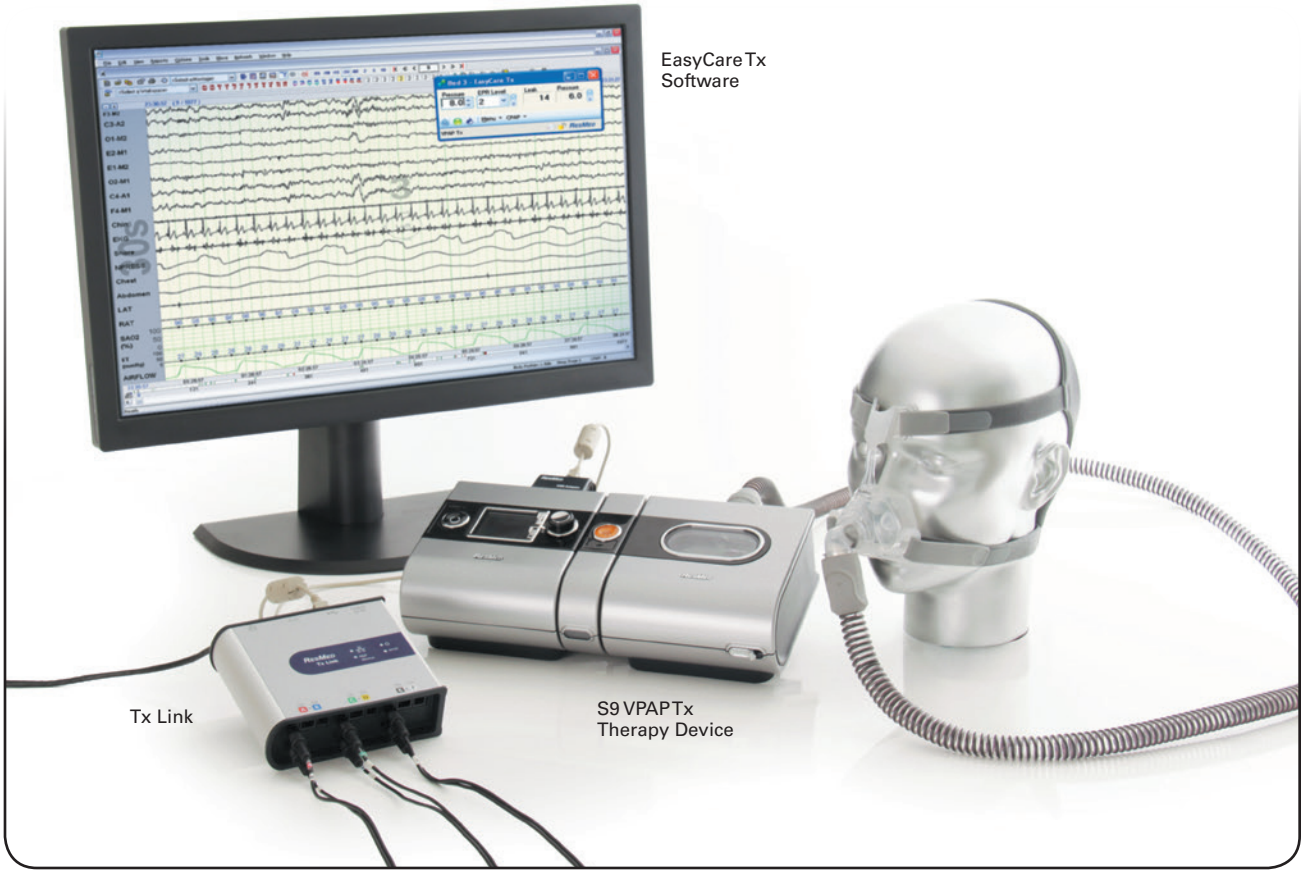
- On-screen remote control of the therapy device
- Highly customized for the clinical environment to help manage a wide range of patients from one system
- Creates summary reports and prescriptions

Tx Link

- Provides connectivity between the software and therapy device
- Seamlessly integrates with all existing major PSG systems, relaying real-time signals measured by the therapy device directly to the polysomnography (PSG) equipment

S9 VPAP Tx therapy device

- Built on the award-winning S9™ platform — small, sleek, silent
- Makes treating a wide range of patients possible with adult and pediatric therapy titration applications
- Uses Climate Control, ResMed's most advanced humidifcation technology, to maximize patient comfort and minimize overall titration pressure



Delivering Efficient, Consistent Results

Patient comfort features

Climate Control humidification technology intelligently adapts to environmental conditions and delivers optimal temperature and humidity right to the mask via ClimateLine™ tubing. Our Climate Control technology simplifies titration while significantly reducing rainout and dryness issues, which can lead to an average increase in usage of 30 minutes.[1]

Working together with the whisper-quiet motor, Easy-Breathe waveform and user-friendly design, the S9 VPAP Tx enables technicians to provide patients a comfortable, easy-going experience for their first night on therapy.

Whisper-quiet operation minimizes therapy disruptions—as one of the quietest home therapy devices on the market—now available in our all-in-one lab titration device (26dBA).

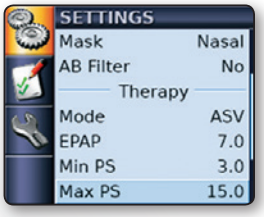
Sleep lab efficiency features

ResMed's award-winning S9 platform makes patient therapy acceptance simple with all of ResMed's essential and advanced modes, now on the award-winning S9 platform.

Intuitive and easily customizable software reduces training time and allows navigation and control of all settings at the bedside and control room, enabling technicians to manage multiple patients across a spectrum of disorders in the same night for increased efficiency.

Mask Fit feature displays real-time leak when fitting the mask at the bedside and ensures the selected mask has a proper seal before starting titration.

Color LCD provides quick access to therapy settings for easy device navigation at the patient's bedside.

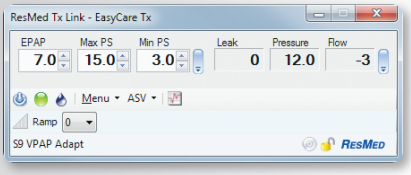


Guided mode transitions eliminate sudden changes in pressure and enable a smooth transition from one mode or pressure to another.

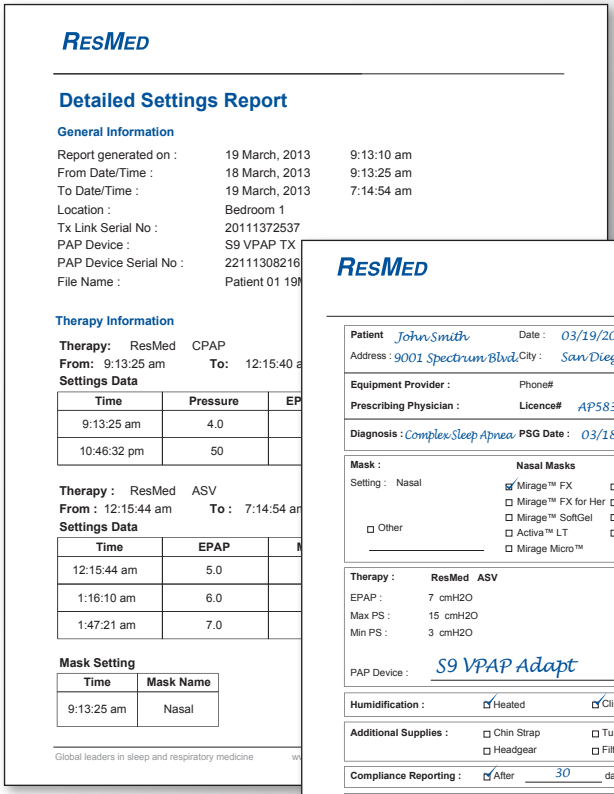
Customizable default settings enable customization of therapy settings according to your lab protocols.

Prescription and Detailed Settings reports capture all changes made to therapy pressures and settings during the night and can be easily generated and edited, minimizing study turnaround times by incorporating final mask and device settings into a script.

True Leak reporting automatically displays accurate mask leak data, eliminating the need to reference charts to calculate appropriate leak values.



EasyCare Tx software has a user-friendly toolbar that allows remote control of a therapy device while displaying current therapy settings.



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Detailed Settings Report

General Information

Report generated on :	19 March, 2013	9:13:10 am
From Date/Time :	18 March, 2013	9:13:25 am
To Date/Time :	19 March, 2013	7:14:54 am
Location :	Bedroom 1	
Tx Link Serial No :	20111372537	
PAP Device :	S9 VPAP TX	
PAP Device Serial No :	22111308216	
File Name :	Patient 01 19M	

Therapy Information

Therapy: ResMed CPAP
From: 9:13:25 am **To:** 12:15:40 a
Settings Data

Time	Pressure	EP
9:13:25 am	4.0	
10:46:32 pm	50	

Therapy : ResMed ASV
From : 12:15:44 am **To :** 7:14:54 ar
Settings Data

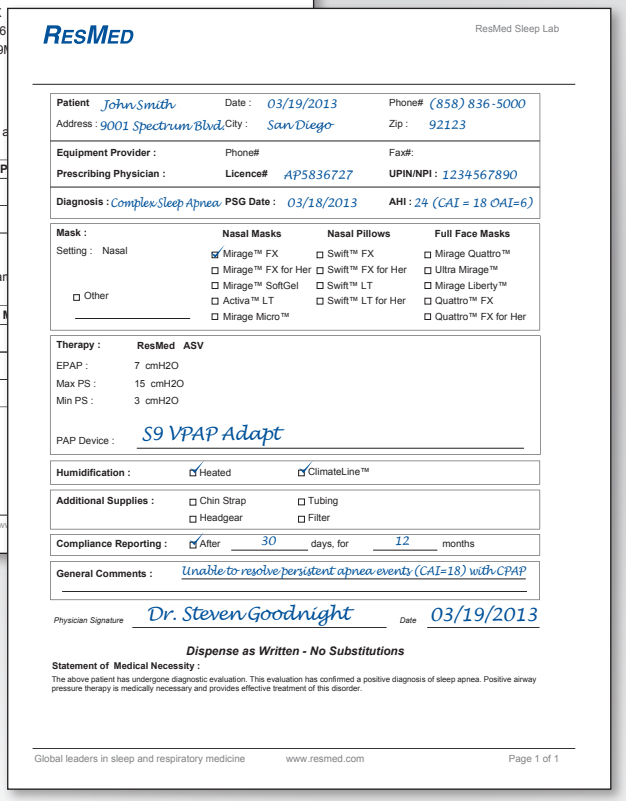
Time	EPAP	M
12:15:44 am	5.0	
1:16:10 am	6.0	
1:47:21 am	7.0	

Mask Setting

Time	Mask Name
9:13:25 am	Nasal

Global leaders in sleep and respiratory medicine

Detailed Settings Report



ResMed

ResMed Sleep Lab

Patient John Smith Date : 03/19/2013 Phone# (858) 836-5000
Address : 9001 Spectrum Blvd City : San Diego Zip : 92123

Equipment Provider : Phone# Fax#:
Prescribing Physician : Licence# AP5836727 UPIN/NPI : 1234567890

Diagnosis : Complex Sleep Apnea PSG Date : 03/18/2013 AHI : 24 (CAI = 18 OAI=6)

Mask :
Setting : Nasal
☐ Other

Nasal Masks	Nasal Pillows	Full Face Masks
☑ Mirage™ FX	☐ Swift™ FX	☐ Mirage Quattro™
☐ Mirage™ FX for Her	☐ Swift™ FX for Her	☐ Ultra Mirage™
☐ Mirage™ SoftGel	☐ Swift™ LT	☐ Mirage Liberty™
☐ Activa™ LT	☐ Swift™ LT for Her	☐ Quattro™ FX
☐ Mirage Micro™		☐ Quattro™ FX for Her

Therapy : ResMed ASV
EPAP : 7 cmH2O
Max PS : 15 cmH2O
Min PS : 3 cmH2O
PAP Device : S9 VPAP Adapt

Humidification : ☑ Heated ☑ ClimateLine™

Additional Supplies : ☐ Chin Strap ☐ Tubing ☐ Headgear ☐ Filter

Compliance Reporting : ☑ After 30 days, for 12 months

General Comments : Unable to resolve persistent apnea events (CAI=18) with CPAP

Physician Signature Dr. Steven Goodnight Date 03/19/2013

Dispense as Written - No Substitutions

Statement of Medical Necessity :
The above patient has undergone diagnostic evaluation. This evaluation has confirmed a positive diagnosis of sleep apnea. Positive airway pressure therapy is medically necessary and provides effective treatment of this disorder.

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Prescription Report

1 Wimms AJ, Richards GN, Benjafield et al. Adherence comparison of a new CPAP system in sleep disordered breathing. *Sleep* 2011

ResMed Therapy Modes and Clinically Superior Algorithms

The S9 VPAP Tx puts access to all of our advanced titration modes at your fingertips to provide complete care across the full range of sleep disorders.

ResMed technologies like iVAPS and ASVAuto—our unique bilevel modes—combine with innovative features like TiControl™ to make it easy and efficient to achieve comfortable, quality patient care.

Adult and pediatric therapy titration applications like CPAP, VPAP S, ST, T and PAC therapy modes are FDA cleared to treat patients weighing 30 lb (>13 kg) and above regardless of age, allowing sleep labs to provide titration for a wider range of patients—including pediatrics.

- **CPAP** – Fixed pressure delivered with optional expiratory pressure relief (EPR™)
- **AutoSet™** – Automatically adjusts pressure in response to snore, flow limitation and obstructive sleep apneas with no pressure support
- **VPAP (Bilevel)** – Delivers two treatment pressures—one for inspiration (IPAP) and one for expiration (EPAP)—and provides control over the following bilevel therapy modes:
  - » **S (Spontaneous)** – Follows the natural breathing pattern, allowing patients to breathe at their regular respiratory rate and rhythm
  - » **S/T (Spontaneous/Timed)** – Augments any breaths initiated by the patient, but will also supply additional breaths if the breath rate falls below the clinician's set "backup" respiratory rate
  - » **PAC (Pressure Assist Control)** – The inspiration time is preset in the PAC mode. There is no spontaneous/flow cycling. The inspiration can be triggered by the patient when respiratory rate is above a preset value, or time-triggered breath will be delivered at the backup breath rate.
  - » **T (Timed)** – The fixed respiratory rate and the fixed inspiration/expiration time set by the clinician are supplied regardless of patient effort
  - » **VAuto** – Automatically adjusts pressure in response to flow limitation, snore and apneas; pressure support (PS) is fixed throughout the night and can be set by the clinician
  - » **Adaptive Servo-Ventilation (ASV and ASVAuto)** – Treats the spectrum of central breathing disorders, including mixed sleep apnea, complex sleep apnea (CompSA) and periodic breathing such as Cheyne–Stokes respiration (CSR)
  - » **iVAPS** – Treats hypercapnic respiratory insufficiency, including obesity hypoventilation, chronic obstructive pulmonary disease, neuromuscular disease and restrictive conditions

1 EPR available in CPAP and AutoSet modes

Technical Specifications

Pressure Ranges

CPAP
4–20 cm H_2O (EPR 0-3)

AutoSet™
APAP 4–20 cm H_2O (EPR 0-3)

Bilevel (S, S/T, T, PAC)
EPAP 3–25 cm H_2O, IPAP 4–30 cm H_2O

VAuto
EPAP 4–25 cm H_2O, IPAP 4–25 cm H_2O

ASV and ASVAuto
EPAP 4–15 cm H_2O,
Pressure Support 0–20 cm H_2O

IVAPS
EPAP 3–25 cm H_2O,
Pressure Support 0–27 cm H_2O

Filter
Two-layered, powder-bonded, polyester non-woven fiber

Altitude Compensation
Automatic

Electrical Requirements
100–240 V

DC Power
Direct connect cord

EasyCare Tx Software

Minimum Hardware and Software Requirements

PC (Mac not supported)

Pentium 1 GHz CPU

1 GB RAM

1024 x 768 display resolution

10/100 Mbps Ethernet Port

Microsoft Windows Vista, Windows XP ≥ SP2 or Windows 2007

Microsoft .NET Framework 2.0

Cat5 cable or available network port between patient room and control room

S9 VPAP Tx Accessories

H5i™ Cleanable Tub	36800
H5i Standard Tub	36803
ClimateLine™	36995
ClimateLine^{MAX} Oxy	36996
Filter (1 Pack)	36850
Filter (2 Pack)	36851
Filter (12 pack)	36852
Filter (50 pack)	36853

Getting Started

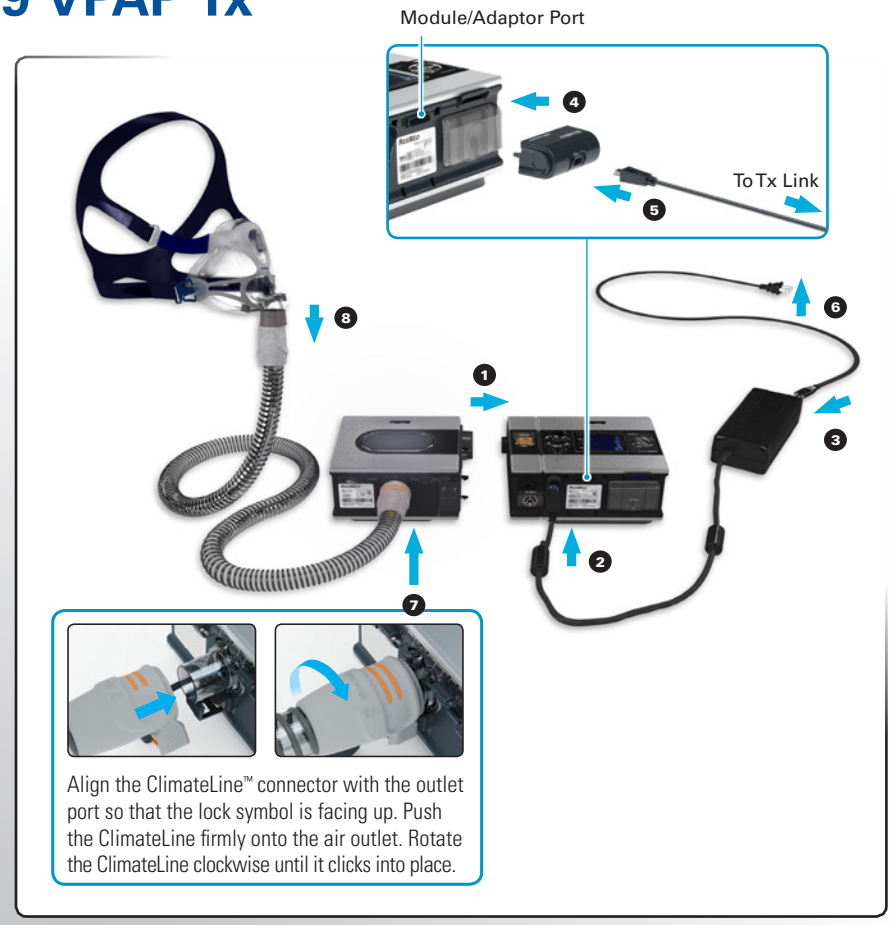
S9 VPAP™ Tx Control Panel

	Key	Function
	Start/Stop button	Starts or stops treatment. Power Save mode—hold for three seconds.
	Info menu button	Allows you to view the device service information or to exit from the menu.
	Setup menu button	Allows you to make changes to settings or to exit from the menu.
	Push dial	Turning the dial allows you to scroll through the menu and change settings. Pushing the dial allows you to enter into a menu and confirm your choice.
	Alarm mute button	Press once to mute alarms. Press a second time to un-mute. If the problem is still present, the alarm will sound again after two minutes.
	LCD screen	Displays the menus, treatment screens and reminders.
	LCD screen backlight	When treatment is being delivered, the backlight (including the Start/Stop button) automatically turns off after 30 seconds, otherwise it turns off after three minutes.
	Alarm LED	Yellow LED—flashes during an alarm.
	Therapy LED	Blue LED—always on during therapy (if enabled in the Options menu).

At the Bedside

Setting Up the S9 VPAP Tx

1. Align the H5i with the S9 VPAP Tx and push them together until they click into place.
2. Connect the DC plug of the power supply unit to the rear of the S9 VPAP Tx.
3. Connect the power cord to the power supply unit.
4. Plug the USB Module into the Module/ Adaptor port at the rear of the S9 VPAP Tx.
5. Connect the S9 VPAP Tx to the Tx Link via the USB serial cable.
6. Plug the other end of the power cord into the power outlet.
7. Connect one end of the air tubing firmly onto the air outlet.
8. Connect the assembled mask system to the free end of air tubing.



Align the ClimateLine™ connector with the outlet port so that the lock symbol is facing up. Push the ClimateLine firmly onto the air outlet. Rotate the ClimateLine clockwise until it clicks into place.

Filling the H5i Water Tub

The S9 VPAP Tx is compatible with the integrated H5i heated humidifier. For further information on using this humidifier refer to the H5i user guide.

Slide the silver latch on the front of the device and lift open the flip lid. **Remove the water tub.**

Through the center hole, fill the water tub with room temperature (do not use hot or cold) distilled water up to the max water level mark (380 mL).

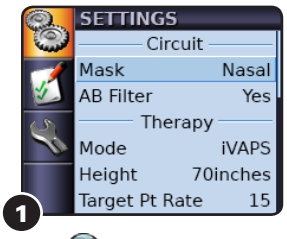
Filling water tub while still in humidifier may damage unit.

Overfilling the water tub may result in water splashing through the tubing.

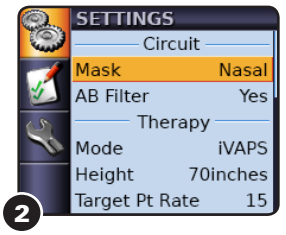
Return the water tub to the H5i.

Close the flip lid, ensuring that it clicks into place.

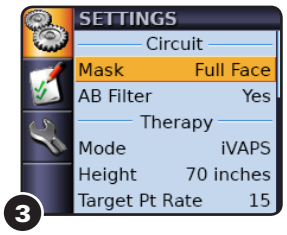
Navigating the Menus



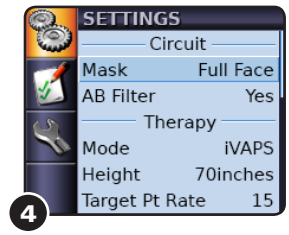
Turn until the parameter you require is displayed in blue.



Press . The selection is highlighted in orange.



Turn until you see the setting that you require.



Press to confirm your choice. The screen returns to blue.

Mask Type and Tube Type Settings

Use the following settings below for each mask type:

Mask type	Settings
Full Face	Full Face
Pillows	Pillows
Nasal	Nasal (for Ultra Mirage mask, use 'Nasal Ultra')
Pediatric	Pediatric

Notes:

- For more information on assembling the mask, see the mask user guide.
- For a complete list of recommended masks and their settings go to www.resmed.com on the **Products** page under **Service & Support**. If you do not have Internet access, please contact your ResMed representative.

The S9 VPAP Tx is compatible with the following air tubing:

Air tubing	Specifications	Settings
ClimateLine	Heated Length: 6'6" (2 m) Inner diameter: 0.6" (15 mm)	Automatically detected
ClimateLine^{MAX} Oxy	Heated Length: 6'3" (1.9 m) Inner diameter: 0.75" (19 mm)	Automatically detected
ClimateLine^{MAX}	Heated Length: 6'3" (1.9 m) Inner diameter: 0.75" (19 mm)	Automatically detected
SlimLine	Length: 6' (1.8 m) Inner diameter: 0.6" (15 mm)	If using the SlimLine, Standard or 3 m air tubing, adjust the tube setting via the Setup menu.
Standard	Length: 6'6" (2 m) Inner diameter: 0.75" (19 mm)	
3 m	Length: 9'10" (3 m) Inner diameter: 0.75" (19 mm)	

Note:

The ClimateLine, ClimateLine^{MAX} and ClimateLine^{MAX} Oxy are designed only for use with the H5i.

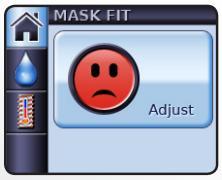
Mask Fit

Mask Fit is designed to help fit the mask properly to the patient.

The Mask Fit feature delivers CPAP pressure for a three-minute period, prior to starting treatment. During this time, the mask can be adjusted to minimize leaks.

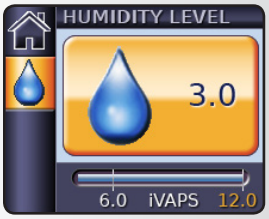
To use Mask Fit:

- Fit the mask as described in the mask user guide.
- Press for at least three seconds. One of the MASK FIT screens is displayed (as shown on the right).
- If necessary, adjust the mask, mask cushion and headgear until there is a secure and comfortable fit. After three minutes, the pressure reverts to the set pressure and treatment will begin. You can end Mask Fit at any time by pressing .

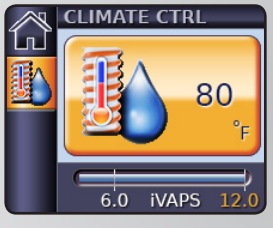


Viewing the Treatment Screens

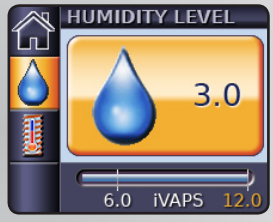
Depending on how the system has been configured and what mode has been selected, you will see one of the following example screens (shown in iVAPS mode below) when the device is running:



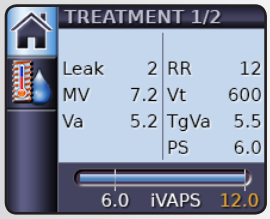
✓ H5i humidifier



✓ H5i humidifier
✓ ClimateLine/ClimateLine[MAX]
✓ Climate Control – Auto



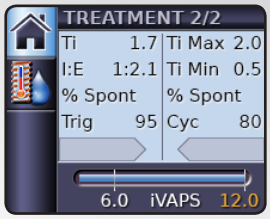
✓ H5i humidifier
✓ ClimateLine/ClimateLine[MAX]
✓ Climate Control – Manual



✓ Therapy data

To toggle between the treatment screens, press from your HOME screen.

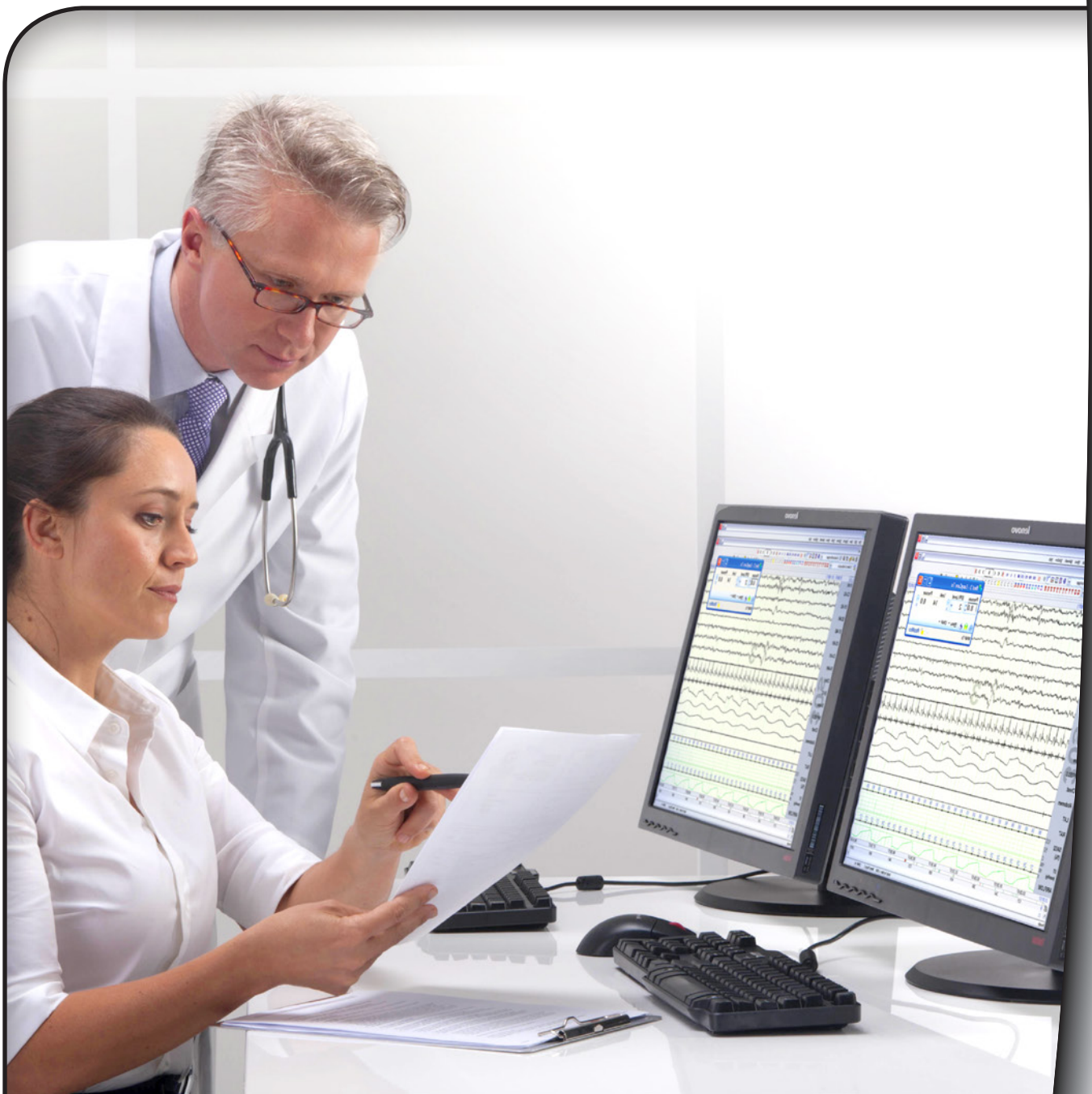
✓ Treatment with device trigger (Timed) and cycle (Timed, Ti Max or Ti Min) breath indicators



✓ Treatment with spontaneous trigger and cycled breaths

Pressure bar:
In bilevel modes, the pressure bar is marked with fixed vertical lines indicating the expiratory and inspiratory pressures. In CPAP and AutoSet modes, only a set pressure is shown.

In the Control Room



Starting a Session

Before you start titrating a patient, you need to start EasyCare Tx and then start a titration session.

To start a titration session:

1. Double-click the EasyCare Tx icon on the Desktop. The EasyCare Tx toolbar is displayed and the default Tx Link is automatically connected. (If the Tx Link is not automatically connected, connect to a Tx Link.)
2. Configure Mask and Humidifier Settings.
3. Click the *Therapy Start/Stop*® icon. Titration begins and the therapy indicator turns green.

ResMed EasyCare Tx

Note:

The Therapy ON/OFF indicator turns green during therapy and gray when therapy is off.

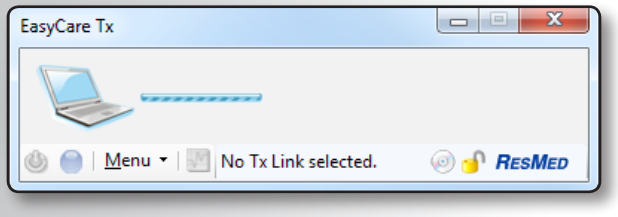
Manual Connection to a Tx Link

Connecting to a Tx Link

If you do not specify a default Tx Link in User Preferences, the following window is displayed every time you launch EasyCare Tx. From this window you can connect to any Tx Link on the network.

To connect to Tx Link:

1. From the *Menu* drop-down, click *Connect*. The *Select Device* window is displayed.
2. Select the required Tx Link from the *Connect To* drop-down list.
3. Click *OK*. A window indicating that EasyCare Tx is establishing a connection with Tx Link is displayed.



Within a few seconds, EasyCare Tx will connect to the Tx Link.

Connectivity issues

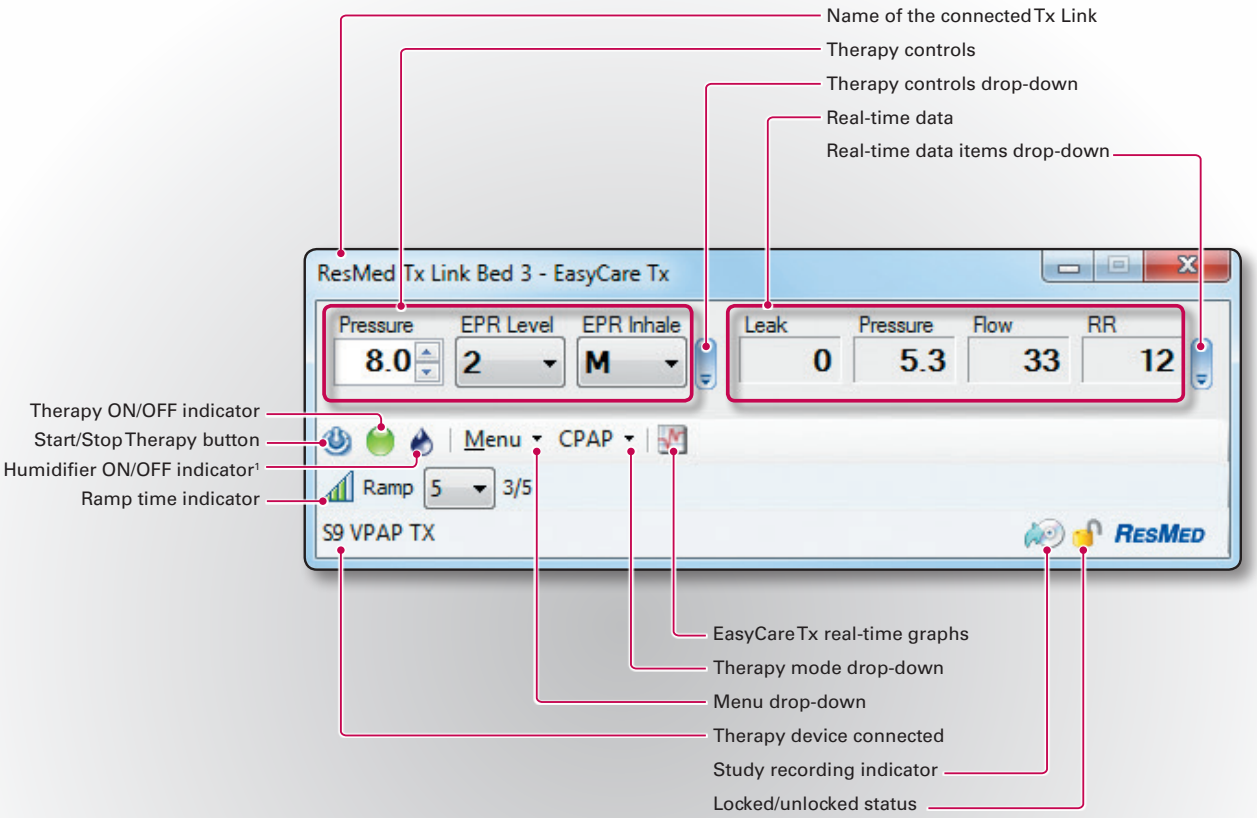
You may experience connectivity issues in the following circumstances:

- EasyCare Tx is unable to connect to the Tx Link;
- EasyCare Tx loses connectivity with the Tx Link;
- Tx Link is unable to connect to the therapy device; or
- Tx Link loses connectivity with the therapy device.

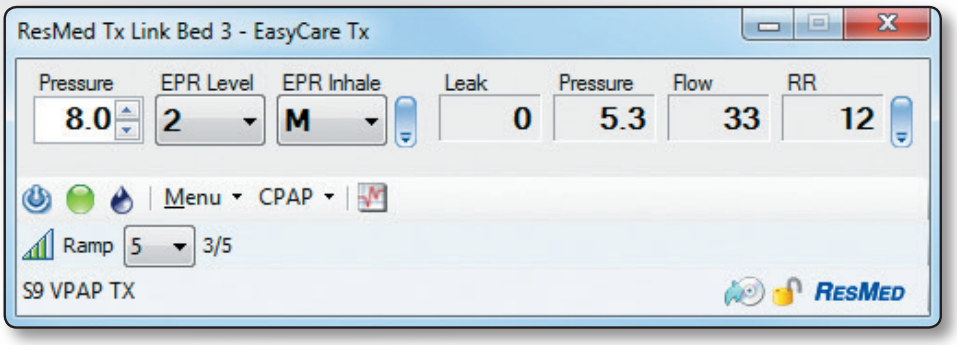
In such instances, a window indicating the connectivity status is displayed and this helps you to take the appropriate action to restore connectivity. For instructions on resolving these issues, refer to troubleshooting in the S9 VPAP Tx Clinical Manual.

EasyCare Tx Toolbar Overview

EasyCare Tx is designed as a user-friendly toolbar and allows remote control of a therapy device while displaying current therapy settings.



Toolbar shown without callouts for clarity.



1 The Humidifier icon is only displayed if the connected therapy device has a humidifier that can be remotely controlled.

Configuring Mask and Humidifier Settings

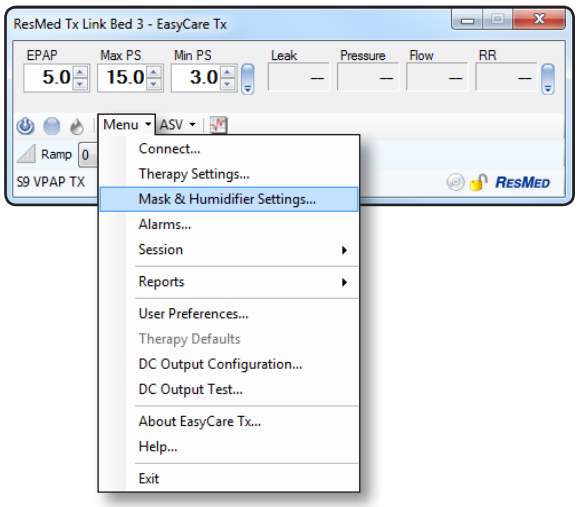
Configuring circuit settings

Before starting therapy, select the mask type used by the patient and review the humidifier settings.

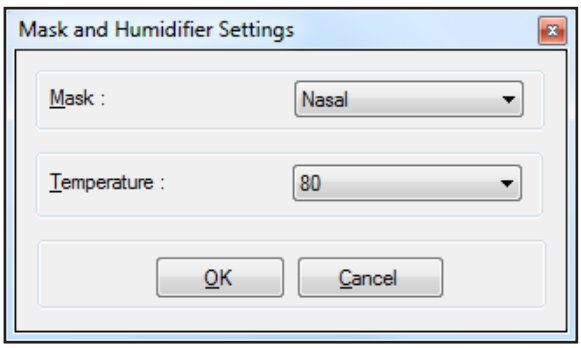
- **Mask Settings**
  Mask Settings can be specified either at the bedside from the therapy device, or remotely using EasyCare Tx.
- **Humidifier Settings**
  EasyCare Tx automatically provides humidifier controls relevant to the therapy device and H5i humidifier connected. Refer to the clinical guides provided with the therapy device and humidifier.

To configure circuit settings:

1. From the *Menu* drop-down, click *Mask* and *Humidifier Settings*. The Mask and Humidifier Settings window is displayed.



2. Select the required mask type from the *Mask* drop-down list.
3. Select the desired humidifier option from the *Humidifier* drop-down list, or the desired temperature setting from the *Temperature* drop-down list.
4. Click OK. The mask and humidifier settings are applied to EasyCare Tx.



Adjusting Therapy Settings

Therapy settings

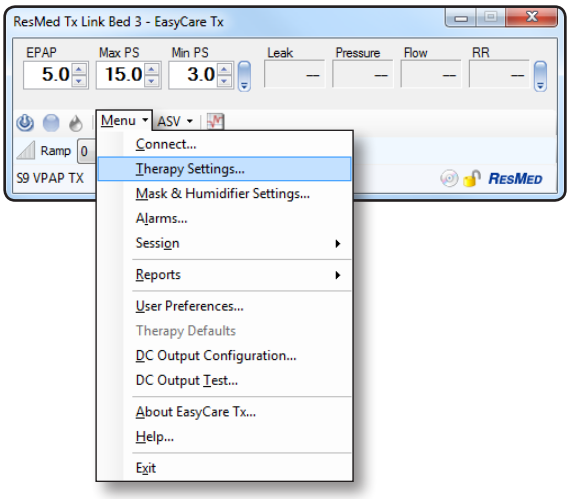
Therapy settings can be controlled in two ways:

- By adjusting individual parameters displayed on the toolbar
- Using the Therapy Settings window

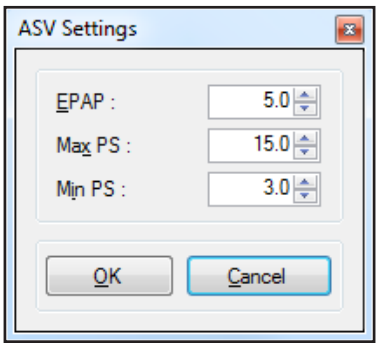
When adjusting individual parameters displayed on the toolbar, the changes are applied instantly. If a confirmation is not sent from the therapy device within two seconds, the parameter will revert to the original value. Alternatively, using the Therapy Settings window, changes are made to one or more parameters related to a therapy and on clicking OK.

To adjust therapy settings from the Therapy Settings window:

1. From the *Menu* drop-down, select *Therapy Settings*. The current therapy settings window is displayed.



2. Change the appropriate therapy settings as required.
3. Click *OK*. The updated therapy settings are applied to EasyCare Tx.



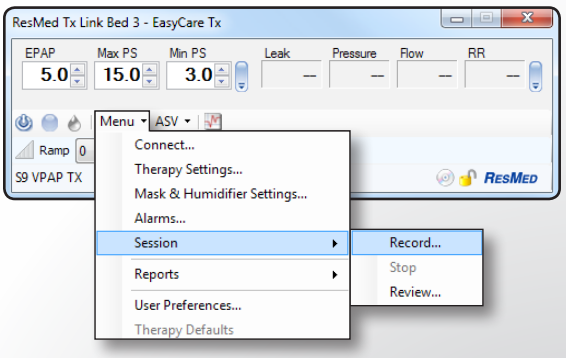
Detailed Settings Report

Note: The session must be recorded to generate a Detailed Settings Report.

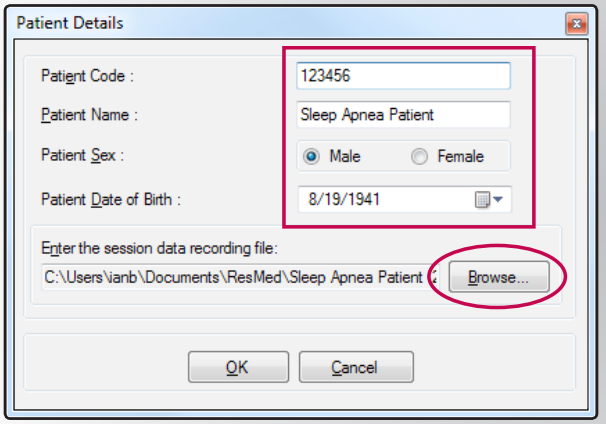
An easy and efficient way to capture and display all pressure, mode and settings changes made during a session.

❶ Record the session prior to starting therapy

a. From the *Menu* drop-down, select *Session* > *Record*



b. Populate the patient details in the pop-up window and click *Browse* to pull up the "*Save Session Data*" dialog box



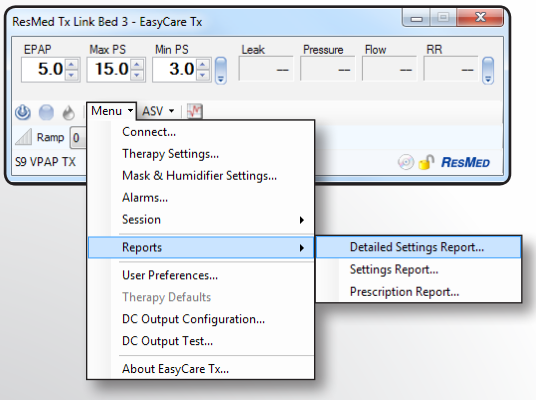
c. Choose a location to save the file, enter the file name and click *Save*

Note: EasyCare Tx will remember and load the previous location selected by the user as default.

d. Click *OK* to begin recording. To stop the recording, select *Session* > *Stop* from the *Menu* drop-down

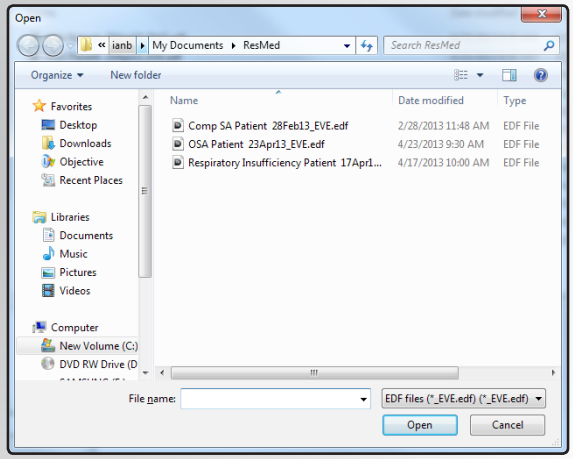
❷ Run and print the Detailed Settings Report

a. From the *Menu* drop-down, select *Reports* > *Detailed Settings Report*

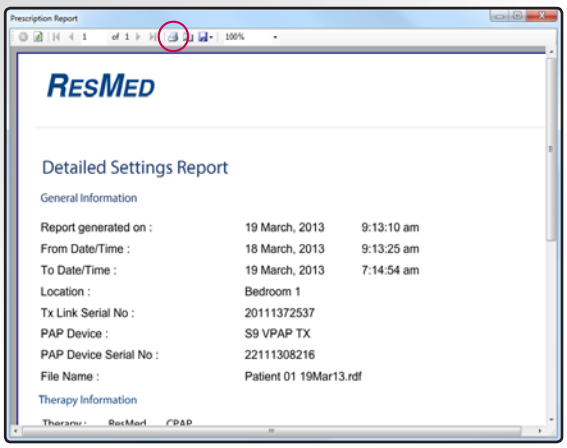


b. Click *Browse* and select the saved patient file

c. Click *Open*, and click *OK* to display the report

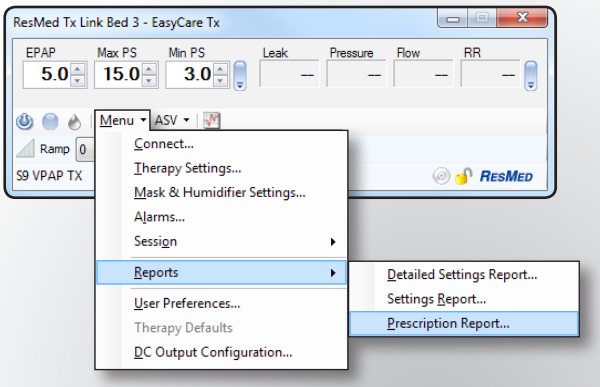


d. Click the *Print* icon to print the report

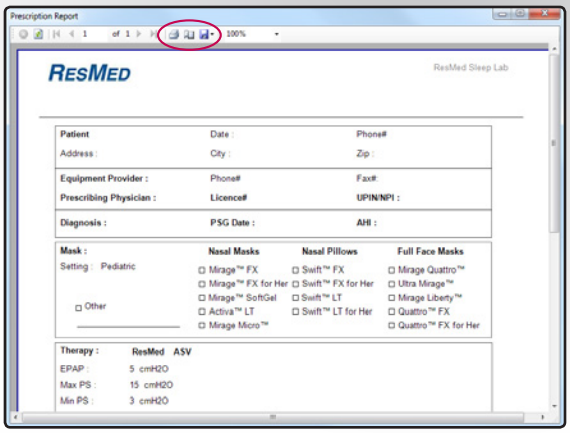

Prescription Report
ResMed
Detailed Settings Report
General Information
Report generated on : 19 March, 2013 9:13:10 am
From Date/Time : 18 March, 2013 9:13:25 am
To Date/Time : 19 March, 2013 7:14:54 am
Location : Bedroom 1
Tx Link Serial No : 20111372537
PAP Device : S9 VPAP TX
PAP Device Serial No : 22111308216
File Name : Patient 01 19Mar13.rdf
Therapy Information

Running and Printing a Prescription Report

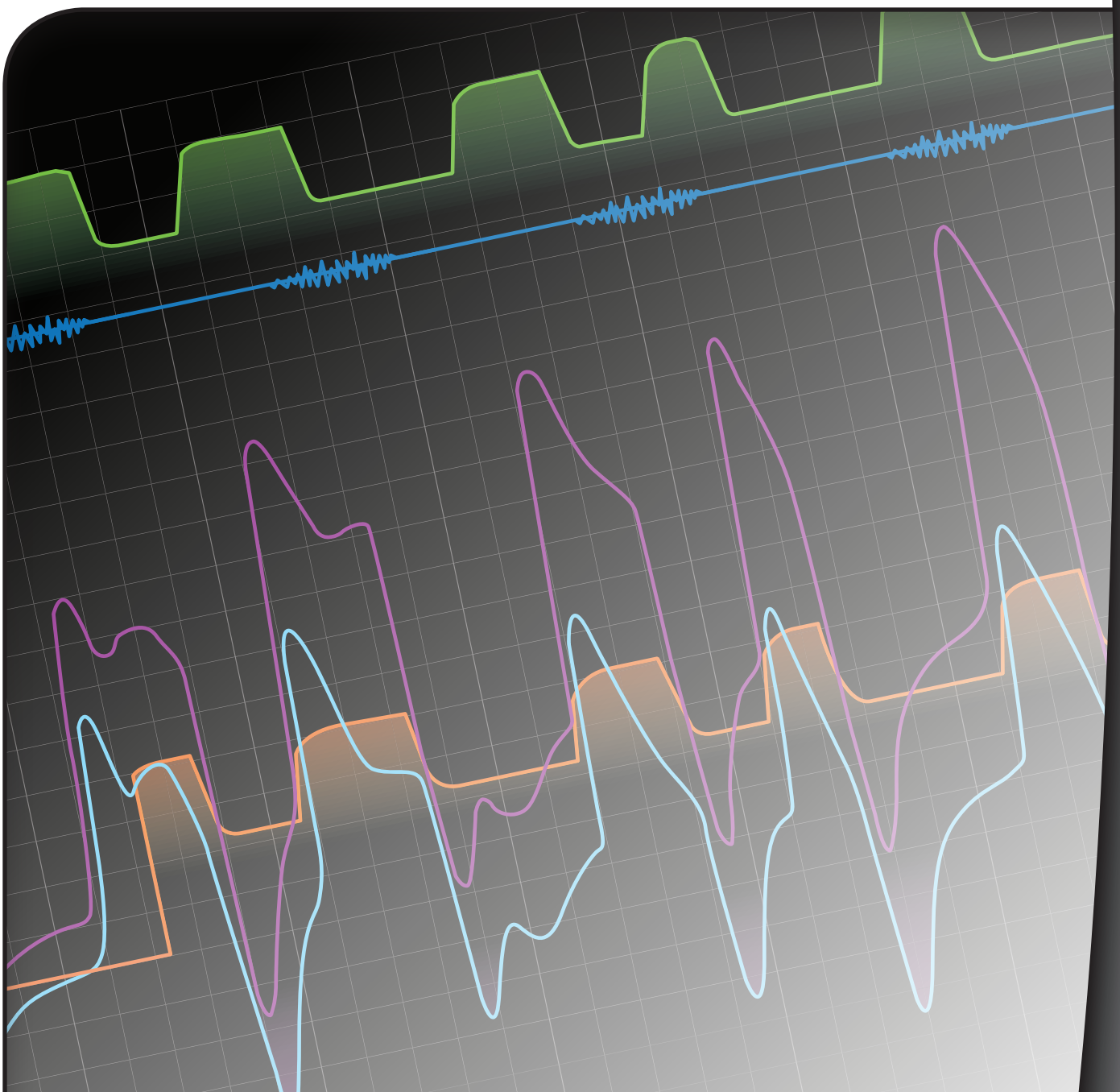
1. From the *Menu* drop-down, select *Reports* > *Prescription Report*.This will open a separate window for the report.



2. Use the print, or save, report button at the top of the screen. Follow standard procedures for your computer.



Technologies



Notes

CPAP and AutoSet™ Technology

ResMed's AutoSet technology

Using a multiple-breath moving average, the AutoSet algorithm continuously monitors breathing and responds immediately to any airway changes, such as flow limitation, snoring and apneas.

Event detection and response

ResMed's AutoSet assesses the severity of the event—whether it is limited flow, snoring or an apnea—determines the best pressure solution, and applies it without delay.

CSA detection

ResMed's S9 AutoSet uses the forced oscillation technique (FOT) to determine the state of the airway during an apnea. When an apnea is detected, small oscillations are added to the pressure to measure airway patency. The CSA algorithm uses the resulting flow and pressure to measure airway patency and differentiate central and obstructive events.

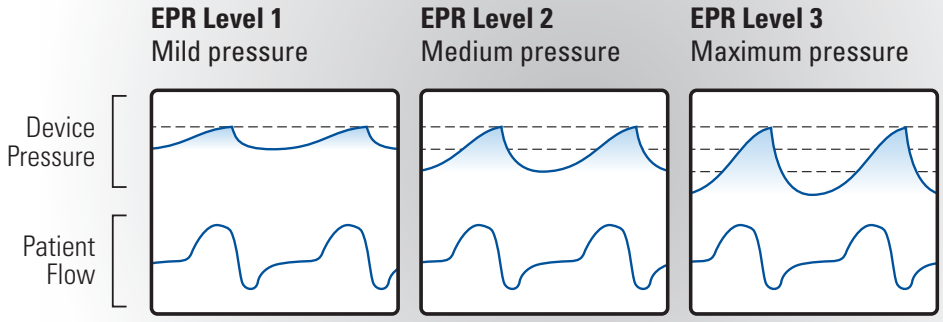
EPR™ and Easy-Breathe

EPR is designed to maintain optimal treatment for the patient during inhalation and reduce the delivered mask pressure during exhalation in the CPAP or AutoSet mode. The desired result of EPR is to decrease the pressure the patient must breathe out against, making the overall therapy more comfortable.

Comfort levels

EPR provides three comfort settings. Each comfort setting correlates to an exact drop in pressure relief:

- EPR Level 1: Mild reduction (1 cm H_2O)
- EPR Level 2: Medium reduction (2 cm H_2O)
- EPR Level 3: Maximum reduction (3 cm H_2O)



Notes:

The numeric value (1, 2 or 3 cm H_2O) for each EPR setting represents the maximum pressure drop during CPAP therapy expiration. Therapy pressure will never drop below 4 cm H_2O. So, for example, if therapy pressure during Ramp Time is 5 cm H_2O and EPR is set at level 3, then the pressure will only reduce to 4 cm H_2O.

For this reason, EPR is a unique comfort feature that ensures therapy effectiveness at all times. EPR allows patient comfort without compromise because the selected setting offers a defined pressure drop value that never exceeds the set value.

VPAP™ Technology

Proven technology, effective treatment

ResMed's VPAP technologies ensure comfortable therapy and enable the clinician to fine-tune settings to a degree not possible in competing products.

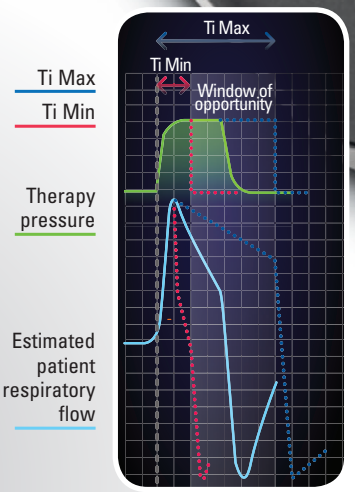
Backup rate, all ResMed Bilevel modes
(not available on VPAP S)

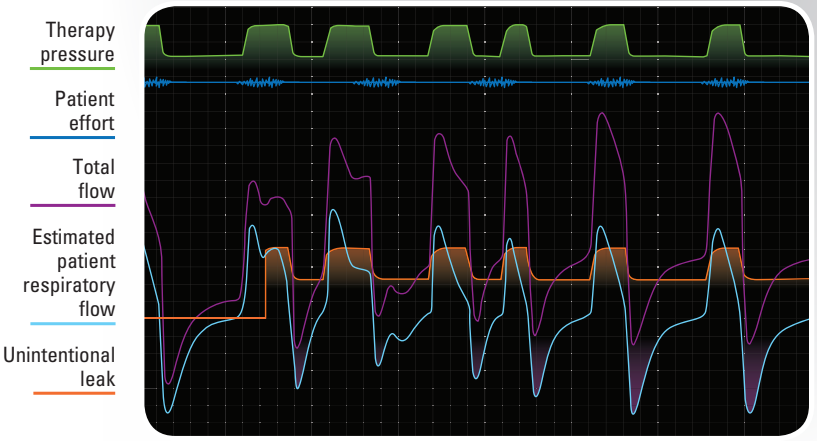
All bilevel modes on S9 VPAP Tx provide a programmable backup rate. The backup rate is manually set in ST, T, PAC and iVAPS modes. It is automatically set in ASV mode.

TiControl™

A number of sophisticated features provide easy access to quality therapy

- Accommodate patients' unique needs with TiControl. Ti Max enables you to set a maximum inspiratory time to reduce the risk of intrinsic PEEP and missed patient effort. Ti Min ensures adequate time for gas exchange without having to increase the pressure setting.
- Better synchrony. Setting a rapid rise time and high cycle sensitivity can help decrease the inspiratory time and extend the expiratory time, resulting in improved patient–ventilator synchrony for patients who are prone to intrinsic PEEP. A slower rise time and lower cycle sensitivity, along with an adequate Ti Min, ensure that patients with weak inspiratory effort have adequate time for gas exchange.
- Adjustable trigger and cycle.
- Adjustable trigger sensitivity supports patients with a weak inspiratory effort, increasing the sensitivity to every patient effort. Adjustable cycle sensitivity is crucial for those at risk for instrinsic PEEP or premature breath cycling.
- Vsync leak compensation. Vsync constantly monitors the flow so that if an unintentional mask leak occurs, the device can quickly compensate for the leak and maintain breathing synchrony.





Patient Setups

These settings are provided as a guideline for initial settings. Individual patients may require further adjustments based on their own conditions. Existing protocols within your facility should always supersede these baseline recommendations.

Please reference the TiControl guide on page 24 for correlating Ti Max/Ti Min settings appropriate for each disease state and adjust based on patient's resting respiratory rate.

Obstructive lung disease

Recommended Settings	Obstructive Lung Disease
IPAP [cm H_2O]	13
EPAP [cm H_2O]	5
Ti Max [sec][1]	1.0
Ti Min [sec][1]	0.3
Rise time [ms][2]	150
Trigger sensitivity	Medium
Cycle sensitivity	High
PS [cm H_2O]	8

Patients with obstructive lung disease have chronic airflow limitation. These patients have particular difficulty exhaling air, which leads to air trapping and hyperinflation. These patients require a longer exhalation, which often leads to asynchrony with standard bilevel settings.

The recommended settings use a faster rise time to ensure that the lungs are filled quickly, and a high cycle sensitivity to provide an earlier cycle to exhalation. The rapid inhalation and prolonged exhalation will help to prevent auto-PEEP and preserve synchrony.

Restrictive lung disease

Recommended Settings	Restrictive Lung Disease
IPAP [cm H_2O]	11
EPAP [cm H_2O]	5
Ti Max [sec][1]	1.5
Ti Min [sec][1]	0.8
Rise time [ms][2]	300
Trigger sensitivity	High
Cycle sensitivity	Low
PS [cm H_2O]	6

Patients with restrictive lung disease have a difficult time maintaining the inhalation phase long enough to ensure adequate tidal volume and gas exchange. This can be caused by a physical restriction of the lungs or by neuromuscular weakness.

The recommended settings use a low cycle sensitivity and a longer Ti Min time to provide a longer inhalation time to help increase tidal volume and gas exchange.

Obesity hypoventilation syndrome (OHS)

Recommended Settings	Obesity Hypoventilation Syndrome
IPAP [cm H_2O]	15
EPAP [cm H_2O]	7
Ti Max [sec][1]	1.5
Ti Min [sec][1]	0.8
Rise time [ms][2]	300
Trigger sensitivity	Medium
Cycle sensitivity	Medium
PS [cm H_2O]	8

Obesity hypoventilation patients often have reduced tidal volumes due to the additional weight pressing down on the chest and abdomen. Additionally, these patients may also have obstructive sleep apnea (OSA) caused by excess tissue in the upper airway and a high body mass index (BMI).

The recommended settings use a higher EPAP pressure to keep the airway open and a higher IPAP to provide additional pressure support and ventilatory assistance.

Normal lungs

Recommended Settings	Normal Lung Mechanics
IPAP [cm H_2O]	11
EPAP [cm H_2O]	5
Ti Max [sec][1]	2.0
Ti Min [sec][1]	0.3
Rise time [ms][2]	300
Trigger sensitivity	Medium
Cycle sensitivity	Medium
PS [cm H_2O]	6

Patients with normal lungs may use NIV in an institutional environment post surgery or to treat sleep apnea.

The recommended settings provide basic settings for patients with normal lung mechanics.

1 Ti settings based on an observed respiratory rate of 20 bpm.
2 The rise time milliseconds scale is approximate.

Setting TiControl

ResMed TiControl: Ti Min and Ti Max Calculation Guide				
Respiratory Frequency (bpm)	Restrictive		COPD Ti Max	Normal Ti Max
	Ti Max	Ti Min		
30	1.0	0.5	0.7	1.0
29	1.0	0.5	0.7	1.0
28	1.1	0.5	0.7	1.1
27	1.1	0.6	0.7	1.1
26	1.2	0.6	0.8	1.2
25	1.2	0.6	0.8	1.2
24	1.3	0.6	0.8	1.3
23	1.3	0.7	0.9	1.3
22	1.4	0.7	0.9	1.4
21	1.4	0.7	0.9	1.4
20	1.5	0.8	1.0	1.5
19	1.6	0.8	1.0	1.6
18	1.7	0.8	1.1	1.7
17	1.8	0.9	1.2	1.8
16	1.9	0.9	1.2	1.9
15	2.0	1.0	1.3	2.0
14	2.1	1.1	1.4	2.1
13	2.3	1.2	1.5	2.3
12	2.5	1.3	1.7	2.5

Setting Ti Max and Ti Min using the respiratory rate table:

1. Instruct the patient to breathe normally while comfortably sitting or lying down.
2. Count the patient's respiratory rate (breaths/minute).
3. Considering the patient's respiratory disease, refer to the appropriate range of settings in the table below (restrictive, COPD or normal) to set Ti Max and Ti Min.
4. In the case of COPD or normal lungs, use the Ti Min default setting.

VPAP Technology Q&A

What does the trigger threshold do?

The trigger threshold is the flow in liters/min used by the Vsync™ algorithm to determine the patient's readiness to receive a breath from VPAP (change from EPAP to IPAP). In essence, as you change from Low to High, you're increasing the sensitivity of VPAP to the patient's effort as detected by measuring flow in the breathing circuit.

When should I adjust the trigger sensitivity threshold?

The Medium (default) setting will be ideal for most patients.

Recommend the Low (or Very Low) trigger sensitivity setting for the following conditions:

- Abnormally strong heartbeat, may cause cardiac oscillation and subsequent auto-triggering (triggers before the patient inhales)
- Any time the patient complains that breaths are starting before inhaling

Recommend the High (or Very High) trigger sensitivity setting for the following conditions:

- Patients with very weak respiratory effort (eg, neuromuscular diseases)
- Any time the patient complains or there is evidence that the device doesn't seem to respond to inspiratory effort

Note: COPD patients may benefit, but they may benefit from an increase in EPAP to compensate for auto PEEP or intrinsic PEEP. This should be evaluated first before considering the High trigger sensitivity setting.

What does the cycle threshold do?

The cycle threshold is used by the Vsync algorithm to determine the patient's readiness to begin exhaling (change from IPAP to EPAP). VPAP targets a percent of the peak flow used in each breath. For instance, the Medium setting targets 25% of the peak flow as the point where the patient is ready to begin exhalation. The High setting targets 35% and the Low setting targets 15%. As you adjust this setting, the patient may notice a change in the time spent at IPAP.

When should I adjust the cycle sensitivity threshold?

The Medium (default) setting will be ideal for most patients.

Recommend the High (or Very High) cycle sensitivity setting for the following conditions:

- In situations where a shorter inspiratory time is desirable (eg, COPD), whereby a shorter inspiratory time is essential in order to preserve an adequate expiratory time. Ti Max can also be used to shorten inspiratory time
- Any time the patient complains that breaths are too long

Recommend the Low (or Very Low) cycle sensitivity setting for the following conditions:

- In situations where a longer inspiratory time is desirable (eg, neuromuscular diseases or patients with a very weak respiratory effort). Ti Min can also be used to lengthen inspiratory time
- Any time the patient complains that the device seems to switch from IPAP to EPAP too quickly

iVAPS Technology (intelligent Volume-Assured Pressure Support)

For hypercapnic, hypoventilating patients

iVAPS is intelligent air

iVAPS is ResMed's intelligent Volume-Assured Pressure Support, a unique technology that simplifies the process of ensuring appropriate ventilation for the patient and reduces the need for frequent adjustments to therapy over time.

The iVAPS advantage

Intelligent.

Unlike other ventilation modes that only target tidal volume, iVAPS targets alveolar ventilation, accounting for anatomical dead space to ventilate the patient more effectively. iVAPS provides an intelligent Backup Rate (iBR) when necessary while maximizing the patient's opportunity to spontaneously trigger the device.

Personalized.

The Learn Targets feature learns the patient's alveolar ventilation and then sets targets accordingly, giving you a simpler, time-saving option to set up NIV patients. Whether you choose this feature or prefer to set targets directly, iVAPS makes it easy to customize therapy for each patient (Learn Targets not available on S9 VPAP Tx).

Automatic.

iVAPS automatically adjusts the level of pressure support to achieve and maintain the target alveolar ventilation while minimizing sleep disruption.

iVAPS is suitable for adults with respiratory insufficiency conditions, including:

Neuromuscular disease and restrictive conditions
iVAPS can maintain stable ventilation when respiratory effort fluctuates, especially during sleep.

Chronic obstructive pulmonary disease (COPD)
iVAPS may reduce the risk of hyperinflation associated with increased respiratory rate, as compared to therapy targeting tidal volume.

Obesity hypoventilation
When compared to standard pressure support therapy, iVAPS can compensate for changes in respiratory mechanics, such as during nocturnal position changes.

iVAPS Settings

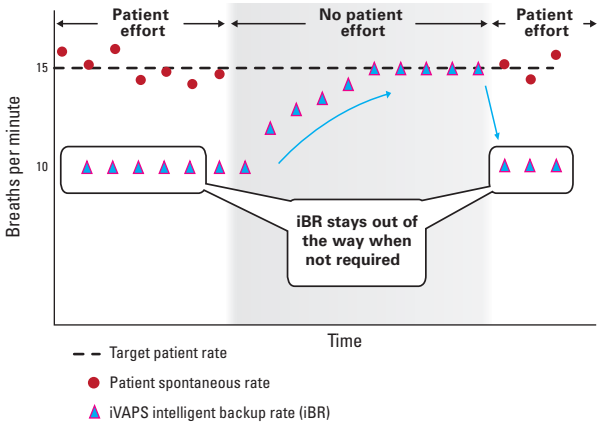
		Recommended Settings
Patient height [inches]		Set appropriate patient height
Target patient rate [bpm]		Set target patient rate equivalent to patient's spontaneous respiratory rate
Target Va		6ml/kg IBW
EPAP	Restrictive lung disease	5 cm H_2O
	Obstructive lung disease	5 cm H_2O
	Obesity hypoventilation syndrome	7 cm H_2O
	Normal	5 cm H_2O
Min PS [cm H_2O]		4
Max PS [cm H_2O]		20
Ramp time		OFF

Notes:

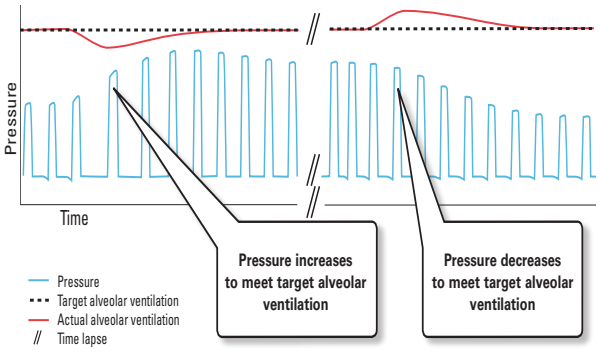
Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient–device synchrony.

Please reference the attached TiControl™ guide for correlating Ti Max/Ti Min settings appropriate for each disease state and adjust based on patient's respiratory rate.

iBR maximizes the patient's opportunity to breathe spontaneously before bringing the patient back to target if backup breaths are required



Automatically changing pressure support and iBR to maintain alveolar ventilation



iVAPS Technology Q&A

Which patients is iVAPS suitable for?

iVAPS is suitable for adults with respiratory insufficiency. It is ideal for patients whose condition is likely to change and is characterized by hypoventilation (day/night hypercapnia). Patient conditions may include:

- Neuromuscular disease and restrictive conditions — iVAPS can maintain stable ventilation when respiratory effort fluctuates
- Obesity hypoventilation — When compared to standard Pressure Support therapy, iVAPS can compensate for changes in respiratory mechanics, such as during nocturnal changes in the patient's body position
- Chronic obstructive pulmonary disease — iVAPS may reduce the risk of hyperinflation associated with increased respiratory rate, as compared to therapy targeting tidal volume

What does iVAPS target?

iVAPS targets alveolar ventilation to deliver required ventilation at the alveoli, where gas exchange occurs. Unlike other volume-assurance modes, iVAPS maintains the alveolar target even when respiratory rate changes.

Why is alveolar ventilation important?

Setting alveolar ventilation targets the patient's true ventilation requirements and represents a more accurate approach.

It's able to deliver the required ventilation at the alveoli, where gas exchange occurs, by taking into account and compensating for the portion of air that travels through the conducting airways.

What are the goals of therapy with iVAPS?

- Optimizing therapy by delivering a set alveolar ventilation with the right pressure at the right time
- Enhancing patient-ventilator synchrony with an intelligent Backup Rate (iBR) to enhance patient comfort
- Minimizing sleep disruption with its rapid, yet gentle response that is quick enough to maintain stable alveolar ventilation, yet smooth enough to maintain sleep quality during nocturnal therapy
- Increased adherence to therapy with iVAPS[1]

1 Jaye J, Kelly J et al. *Eur Respir* J 2012; 40: Suppl. 56, 51

ASV Technology

For normo/hypocapnic, hyperventilating patients

ResMed's ASV is the most clinically studied adaptive servo-ventilation therapy and has been shown to provide effective and comfortable treatment for a range of breathing disorders including obstructive, central and mixed apnea, periodic breathing such as CSR, and CompSA.

ResMed's ASV therapies are available on the VPAP Adapt. Users have the choice of auto-adjusting EPAP in ASVAuto mode or fixed EPAP in ASV mode.

ASVAuto mode adapts to a patient's ventilatory and upper airway stability needs on a breath-by-breath basis. By treating central breathing disorders with auto-adjusting Pressure Support and upper airway obstruction with auto-adjusting EPAP, it rapidly stabilizes breathing to improve blood gases faster and reduce stress on the heart.[1] Simplified patient care is provided through therapy that learns, responds, predicts and optimizes pressures to suit each patient's own unique breathing pattern.

The following summarizes the therapy provided by the ASV mode:

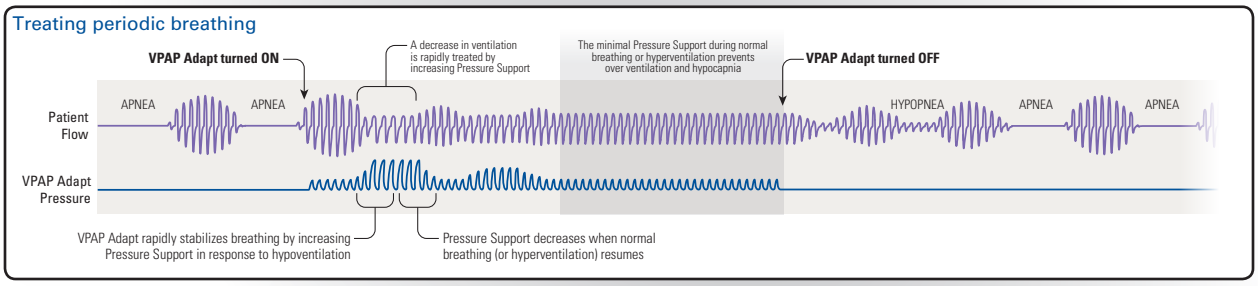
- **Learning continuously for personalized therapy:**
  The only ASV technology to target the patient's own recent minute ventilation, ResMed's ASV continuously learns the patient's own breathing and sets ventilation targets accordingly.
- **Responding rapidly for effective therapy:**
  ResMed's ASV responds within the breath, adjusting Pressure Support to stabilize breathing. In ASVAuto mode, it also stabilizes the upper airway by adjusting EPAP when needed.
- **Predicting each patient's unique needs for ease-of-care:**
  Treating challenging patients has never been easier. ResMed's ASV predictive algorithm learns the patient's unique respiratory rate and delivers pressure matched to the patient's breathing, adapting dynamically to his or her changing needs.
- **Optimizing comfort and synchrony for compliance:**
  Patient comfort is the underlying goal of ResMed's ASV. Proven comfort features such as "ramping" pressure that eases the patient gently into therapy, advanced leak management and ResMed's unique Easy-Breathe pressure waveform provide natural breathing comfort — boosting patient compliance.

1 Hastings et al. *Int J Cardiol* 2010

The Most Responsive Algorithm

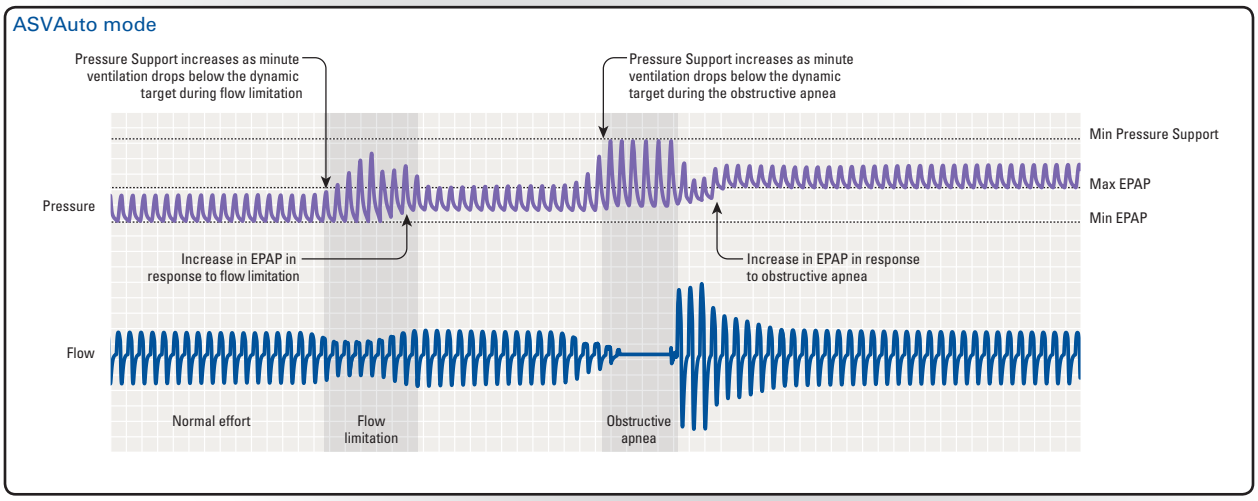
ResMed's ASV targets minute ventilation for optimal therapy outcomes

ResMed's unique ASV algorithm continuously monitors and learns the patient's recent minute ventilation (tidal volume × breathing rate) and sets a target at 90% of this calculation. The Pressure Support then continuously adjusts to reflect the patient's changing needs, reliably and steadily keeping patients on target all through the night. In ASVAuto mode, the EPAP also responds to flow limitation, snore and obstructive apneas on the next breath, in proportion to the severity of the event.


Treating periodic breathing
VPAP Adapt turned ON
A decrease in ventilation is rapidly treated by increasing Pressure Support
The minimal Pressure Support during normal breathing or hyperventilation prevents over ventilation and hypocapnia
VPAP Adapt turned OFF
Patient Flow
APNEA
APNEA
HYPOPNEA
APNEA
APNEA
VPAP Adapt Pressure
VPAP Adapt rapidly stabilizes breathing by increasing Pressure Support in response to hypoventilation
Pressure Support decreases when normal breathing (or hyperventilation) resumes

EPAP response based on AutoSet™ algorithm

- In ASVAuto mode, the auto-adjusting Pressure Support functionality works hand-in-hand with auto-adjusting EPAP, continuously monitoring minute ventilation and respiratory flow to protect breathing.
- The algorithm predicts the onset of airway collapse, assessing the flow shape of each breath. The technology responds to flow limitation and snore, automatically adjusting EPAP in proportion to the severity of the event, to maintain an open upper airway.
- If ventilation decreases away from target, the algorithm increases Pressure Support and monitors how that affects minute ventilation.
- If there is little or no flow during this period, the advanced technology can deduce that the airway is obstructed. Once breathing resumes, it then increases EPAP to prevent further apneas from occurring.
- Once breathing is stabilized, the EPAP gradually decreases towards the minimum EPAP setting for comfort, over a 20–40 minute period, depending on the type of event that occurred.

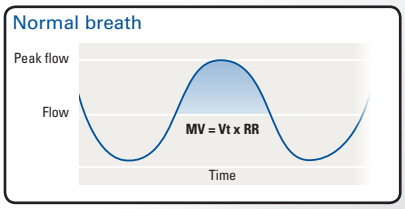

ASVAuto mode
Pressure Support increases as minute ventilation drops below the dynamic target during flow limitation
Pressure Support increases as minute ventilation drops below the dynamic target during the obstructive apnea
Min Pressure Support
Max EPAP
Min EPAP
Pressure
Increase in EPAP in response to flow limitation
Increase in EPAP in response to obstructive apnea
Flow
Normal effort
Flow limitation
Obstructive apnea

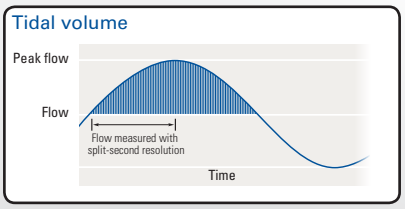
Pressure Support response based on minute ventilation
To successfully treat central and mixed apneas, minute ventilation should be stabilized. This is best achieved by constant monitoring of the patient's breathing pattern, minute ventilation and nimble adjustment of Pressure Support to break the cycle of hyperventilation and central apneas that occur during CSA.

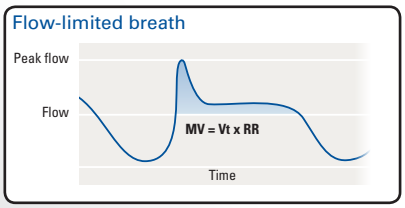
The algorithm achieves this by detecting such apneic events and quickly changing the Pressure Support to control events and normalize tidal volume, thereby normalizing breathing.

Other ASV devices estimate the tidal volume based solely on the peak flow. This can work if every breath is shaped the same, but many breaths have a different flow profile.

As seen in the figures below, ventilation can change substantially without any change to the peak flow of each breath. For this reason, measuring minute ventilation directly enables the most timely and effective pressure changes and, therefore, the best therapy.



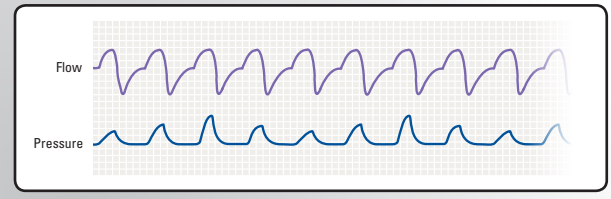


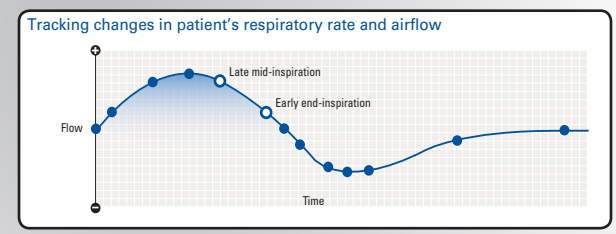


Patient comfort through synchrony

Advanced, predictive technology maximizes comfort and synchrony over a wide range of breath rates
The ASV algorithm continuously learns the patient's own respiratory rate through high-resolution breath phase mapping, maintaining accuracy even at lower breath rates. The algorithm maintains synchrony with the patient's respiratory pattern by learning the rate at which the patient progresses through each breath and dynamically predicting inspiratory and expiratory durations. This enables the VPAP Adapt to deliver pressure that reaches its therapy peak at end-inspiration and its nadir by end-expiration, continuously and smoothly. Additionally, the ResMed leak management feature ensures greater synchrony by offsetting variations and inconsistency due to leak.

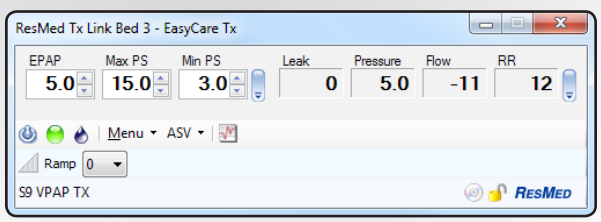
Easy-Breathe for the most natural breathing comfort
Unique to ResMed, the patented Easy-Breathe waveform delivers a smoother, more comfortable breathing experience by replicating the natural wave shape of normal breathing.





Ease of titration

Market-leading simplicity
Minimal settings with empirically selected default parameters are designed to cover the broadest range of patient setups. Unlike competing devices that require setting extra parameters such as Rise Time, ResMed's ASV reduces the need for complicated customization during titration.



ASV Technology Q&A

Which patients is ASV suitable for?

This extensively studied therapy provides demonstrated results across the spectrum of central breathing disorders including:

- Periodic breathing such as Cheyne–Stokes respiration (CSR), both normocapnic and hypocapnic
- Other forms of central and concomitant obstructive events[1] (mixed sleep apnea)
- Complex sleep apnea (CompSA)[2]

ResMed's ASV should also be considered for central sleep apnea (CSA) and ataxic breathing, which is sometimes seen in opioid,[3] neurological and heart failure patients.

What are the goals of therapy with ASV?

- Rapidly stabilizing breathing to stabilize blood gases[4]: The primary goal of ASV therapy is to stabilize ventilation, resulting in normalized $PaCO_2$ levels to encourage stable breathing
- Improving sleep quality and minimizing daytime sleepiness by reducing respiratory-related events
- Improving quality of life[5] through treatment outcomes, ASV helps improve physical performance[4], increase energy and vitality[6]
- Treating complex sleep apnea by adapting automatically to treat both obstructive and central events (in ASVAuto mode)

What does ASV target?

ResMed's ASV therapy continuously learns and adapts targets to reduce short-term oscillations in breathing, keeping ventilation stable. It is the only ASV therapy to target the patient's own recent minute ventilation (MV) and respiratory rate (RR), adapting to changing needs through various sleep stages.

1 Allam et al. Efficacy of adaptive servo-ventilation in treatment of complex and central sleep apnea syndromes. *Chest* 2007; 132(6): p. 1839-46

2 Morgenthaler et al. Adaptive servo-ventilation versus noninvasive positive pressure ventilation for central, mixed, and complex sleep apnea syndromes. *Sleep* 2007; 30(4): p. 468-75

3 Javaheri et al. Adaptive pressure support servo-ventilation: a novel treatment for sleep apnea associated with use of opioids. *J Clin Sleep Med* 2008; 15;4(4): p. 305-10

4 Oldenburg et al. Adaptive servoventilation improves cardiac function and respiratory stability. *Clin Res Cardiol* 2011; 100(2): p. 107-15

5 Topfer et al. Adaptive servo-ventialtion: effect on Cheyne-Stokes-Respiration and on quality of life. *Pneumologie* 2004; 58(1): p. 28-32

6 Hastings et al. Adaptive servo-ventilation in heart failure patients with sleep apnea. *Int J Cardiol* 2010; 139:17-24

Titration Protocols

CPAP and AutoSet Therapy Sample Prescription

RESMED

CPAP Therapy

☐ S9 Elite™

☐ Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR™: ☐1 ☐2 ☐3

APAP Therapy

☒ S9 AutoSet™ DEFAULTS

☐ AutoSet Mode
☐ Default Mode Settings
Min. Pressure:_____cm H_2O (4 cm H_2O) 4
Max. Pressure:_____cm H_2O (20 cm H_2O) 20
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

☒ CPAP Mode
Pressure: 12 cm H_2O (4–20 cm H_2O)
Ramp Time: Off min(s) (OFF–45 min.)
EPR: ☐1 ☒2 ☐3

Bilevel Therapy

☐ S9 VPAP™ Auto DEFAULTS

☐ VAuto Mode
☐ Default Mode Settings
Max. IPAP:_____cm H_2O (4–25 cm H_2O) 25
Min. EPAP:_____cm H_2O (4 cm H_2O–IPAP) 4
PS:_____cm H_2O (0–10 cm H_2O) 4
Ramp Time:_____min(s) (OFF–45 min.)

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

☐ S9 VPAP S

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

Bilevel with Backup Rate Therapy

☐ S9 VPAP Adapt DEFAULTS

☐ ASV Mode
☐ Default Mode Settings
EPAP:_____cm H_2O (4–15 cm H_2O) 5
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ ASV Auto Mode
☐ Default Mode Settings
Min. EPAP:_____cm H_2O (4–15 cm H_2O) 4
Max. EPAP:_____cm H_2O (4–15 cm H_2O) 15
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ S9 VPAP ST

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–30 BPM)

☐ S9 VPAP ST-A

Note: *Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient-device synchrony*

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)

☐ PAC Mode ☐ Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)
Ti:_____sec. (0.1–4 sec.)

☐ iVAPS Mode
Height:_____in. (44–100 in.)
Target Patient Rate:_____BPM (8–30 BPM)
Target Va:_____L/min. (1–30 L/min.)
Vt (Tidal Volume)_____(mL)
Vt/kg_____(mL/kg)
EPAP:_____cm H_2O (3–25 cm H_2O)
Min. PS:_____cm H_2O (0–20 cm H_2O)
Max. PS:_____cm H_2O (0–27 cm H_2O)
☐ Settings to be determined via Learn Targets

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CPAP and AutoSet Therapy Titration Protocol

EPR comfort setting –
Set to patient comfort (1, 2 or 3)

Monitor patient
Is the patient having obstructive events?

YES

Increase CPAP ≥1 cm H_2O every ≥5 mins for obstructive apneas, hypopneas, RERAs and at least 3 min of loud or unambiguous snoring

Continue monitoring patient

Consider trial of bilevel if obstructive events persist at a pressure of 15 cm H_2O

NO

Are events central?

YES

Decrease CPAP by 1 cm H_2O and wait 20 mins. Consider ResMed's ASV if centrals persist and patient meets criteria

NO

Observe patient and document final settings; be sure to document the final CPAP pressure, EPR setting (if any) and ramp time

Indications for CPAP therapy

- Obstructive Sleep Apnea
- Upper Airway Resistance Syndrome

Set mode to CPAP
Initial pressure: 4–5 cm H_2O

A higher pressure may be required for re-titrations, patients with a higher BMI or patients complaining of air hunger or suffocating sensations.

For re-titrations, it is recommended that the pressure be started 2–3 cm H_2O below the patient's current pressure.

VPAP Auto and VPAP S Sample Prescription

RESMED

CPAP Therapy

☐ S9 Elite™

☐ Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR™: ☐1 ☐2 ☐3

APAP Therapy

☐ S9 AutoSet™ DEFAULTS

☐ AutoSet Mode
☐ Default Mode Settings
Min. Pressure:_____cm H_2O (4 cm H_2O) 4
Max. Pressure:_____cm H_2O (20 cm H_2O) 20
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

☐ CPAP Mode
Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

Bilevel Therapy

☒ S9 VPAP™ Auto DEFAULTS

☒ VAuto Mode
☐ Default Mode Settings
Max. IPAP: 25 cm H_2O (4–25 cm H_2O) 25
Min. EPAP: 4 cm H_2O (4 cm H_2O–IPAP) 4
PS: 6 cm H_2O (0–10 cm H_2O) 4
Ramp Time: 15 min(s) (OFF–45 min.)

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

☐ S9 VPAP S

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

Bilevel with Backup Rate Therapy

☐ S9 VPAP Adapt DEFAULTS

☐ ASV Mode
☐ Default Mode Settings
EPAP:_____cm H_2O (4–15 cm H_2O) 5
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ ASV Auto Mode
☐ Default Mode Settings
Min. EPAP:_____cm H_2O (4–15 cm H_2O) 4
Max. EPAP:_____cm H_2O (4–15 cm H_2O) 15
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ S9 VPAP ST

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–30 BPM)

☐ S9 VPAP ST-A

Note: *Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient-device synchrony*

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)

☐ PAC Mode ☐ Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)
Ti:_____sec. (0.1–4 sec.)

☐ iVAPS Mode
Height:_____in. (44–100 in.)
Target Patient Rate:_____BPM (8–30 BPM)
Target Va:_____L/min. (1–30 L/min.)
Vt (Tidal Volume)_____(mL)
Vt/kg_____(mL/kg)
EPAP:_____cm H_2O (3–25 cm H_2O)
Min. PS:_____cm H_2O (0–20 cm H_2O)
Max. PS:_____cm H_2O (0–27 cm H_2O)
☐ Settings to be determined via Learn Targets

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VPAP S Therapy Titration Protocol

(bilevel spontaneous)

Has patient been on CPAP therapy?

YES

Initial settings:

- IPAP = CPAP settings
- EPAP = 4 cm H_2O below IPAP setting

NO

Initial settings:

- IPAP = 8 cm H_2O
- EPAP = 4 cm H_2O

For obstructive apneas:

- Increase EPAP by ≥1 cm H_2O every ≥ 5 min
- Increase IPAP to maintain 4 cm H_2O difference between IPAP/EPAP

For obstructive hypopneas and snoring:

- Increase IPAP ≥ 1 cm H_2O every ≥ 5 min until resolved

Are events central?

YES

Decrease pressure to previous setting, observe for 20 min

If centrals persist, consider adaptive servo-ventilation

NO

For SpO_2 < 90% with all respiratory events eliminated:

- Increase IPAP by ≥ 1 cm H_2O every ≥ 15 min until ≥ 90% SpO_2 is reached
- Follow sleep lab protocols for adding O_2

Observe patient and document final settings, including IPAP/EPAP pressures and TiControl settings if altered from default

Indications for S therapy

- CPAP intolerance
- Continued obstructive events at higher pressures
- Hypoventilation with SpO_2 < 90%
- COPD

VPAP ST Sample Prescription

RESMED

CPAP Therapy

☐ S9 Elite™

☐ Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR™: ☐1 ☐2 ☐3

APAP Therapy

☐ S9 AutoSet™ DEFAULTS

☐ AutoSet Mode
☐ Default Mode Settings
Min. Pressure:_____cm H_2O (4 cm H_2O) 4
Max. Pressure:_____cm H_2O (20 cm H_2O) 20
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

☐ CPAP Mode
Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

Bilevel Therapy

☐ S9 VPAP™ Auto DEFAULTS

☐ VAuto Mode
☐ Default Mode Settings
Max. IPAP:_____cm H_2O (4–25 cm H_2O) 25
Min. EPAP:_____cm H_2O (4 cm H_2O–IPAP) 4
PS:_____cm H_2O (0–10 cm H_2O) 4
Ramp Time:_____min(s) (OFF–45 min.)

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

☐ S9 VPAP S

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

Bilevel with Backup Rate Therapy

☐ S9 VPAP Adapt DEFAULTS

☐ ASV Mode
☐ Default Mode Settings
EPAP:_____cm H_2O (4–15 cm H_2O) 5
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ ASV Auto Mode
☐ Default Mode Settings
Min. EPAP:_____cm H_2O (4–15 cm H_2O) 4
Max. EPAP:_____cm H_2O (4–15 cm H_2O) 15
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ S9 VPAP ST

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–30 BPM)

☒ S9 VPAP ST-A

Note: *Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient-device synchrony*

☒ Spont/Timed Mode
IPAP: 15 cm H_2O (4–30 cm H_2O)
EPAP: 7 cm H_2O (3–25 cm H_2O)
Rate: 15 BPM (5–50 BPM)

☐ PAC Mode ☐ Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)
Ti:_____sec. (0.1–4 sec.)

☐ iVAPS Mode
Height:_____in. (44–100 in.)
Target Patient Rate:_____BPM (8–30 BPM)
Target Va:_____L/min. (1–30 L/min.)
Vt (Tidal Volume)_____(mL)
Vt/kg_____(mL/kg)
EPAP:_____cm H_2O (3–25 cm H_2O)
Min. PS:_____cm H_2O (0–20 cm H_2O)
Max. PS:_____cm H_2O (0–27 cm H_2O)
☐ Settings to be determined via Learn Targets

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VPAP ST Therapy Titration Protocol

(bilevel spontaneous, timed)

Initial settings:

- IPAP = 8 cm H_2O settings
- EPAP = 4 cm H_2O
- Set backup rate at 2–4 below resting respiratory rate

Evaluate and titrate:

- Based on VT, rate, SpO_2 and CO_2 compared to baseline

For obstructive apneas:

- Increase EPAP by ≥1 cm H_2O every ≥5 min
- Increase IPAP to maintain 4 cm H_2O difference between IPAP/EPAP

For residual snoring, hypopneas and/or O_2 desats:

- Increase IPAP ≥1 cm H_2O every ≥ 5 min until resolved

For SpO_2 < 90% with all respiratory events eliminated:

- Increase IPAP by > 1 cm H_2O every ≥15 min until SpO_2 > 90% is reached
- Follow sleep lab protocol for adding O_2

Evaluate VT (tidal volume) if too small:

- Maintain EPAP raise IPAP by 1 cm H_2O every ≥15 min until SpO_2 ≥ 90%

"Exploratory" pressure increase should not exceed 5 cm H_2O

Evaluate if backup rate is adequate:

- Increase backup rate by 1-2 BPM every 20 min as needed

Observe patient and document final pressure settings (IPAP/EPAP pressures, respiratory rate and TiControl settings) if altered from default

Indications for ST therapy

- Neuromuscular/restrictive disorders
- COPD
- Obesity hypoventilation

Continuously monitor sleep and blood gas parameters (including CO_2).

Ensure patient's ventilation levels stay consistent with initial levels, including tidal volume (IPAP–EPAP) and patient respiratory rate versus device backup rate.

Note:
SpO_2, VT and backup rate should be reviewed/monitored throughout the night.

iVAPS Sample Prescription

RESMED

CPAP Therapy

☐ S9 Elite™

☐ Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR™: ☐1 ☐2 ☐3

APAP Therapy

☐ S9 AutoSet™ DEFAULTS

☐ AutoSet Mode
☐ Default Mode Settings
Min. Pressure:_____cm H_2O (4 cm H_2O) 4
Max. Pressure:_____cm H_2O (20 cm H_2O) 20
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

☐ CPAP Mode
Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

Bilevel Therapy

☐ S9 VPAP™ Auto DEFAULTS

☐ VAuto Mode
☐ Default Mode Settings
Max. IPAP:_____cm H_2O (4–25 cm H_2O) 25
Min. EPAP:_____cm H_2O (4 cm H_2O–IPAP) 4
PS:_____cm H_2O (0–10 cm H_2O) 4
Ramp Time:_____min(s) (OFF–45 min.)

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

☐ S9 VPAP S

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

Bilevel with Backup Rate Therapy

☐ S9 VPAP Adapt DEFAULTS

☐ ASV Mode
☐ Default Mode Settings
EPAP:_____cm H_2O (4–15 cm H_2O) 5
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ ASV Auto Mode
☐ Default Mode Settings
Min. EPAP:_____cm H_2O (4–15 cm H_2O) 4
Max. EPAP:_____cm H_2O (4–15 cm H_2O) 15
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ S9 VPAP ST

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–30 BPM)

☒ **S9 VPAP ST-A**

Note: *Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient-device synchrony*

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)

☐ PAC Mode ☐ Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)
Ti:_____sec. (0.1–4 sec.)

☒ iVAPS Mode
Height:_70_in. (44–100 in.)
Target Patient Rate:_18_BPM (8–30 BPM)
Target Va:_4.8_L/min. (1–30 L/min.)
Vt (Tidal Volume)_____(mL)
Vt/kg_____(mL/kg)
EPAP:_8_cm H_2O (3–25 cm H_2O)
Min. PS:_4_cm H_2O (0–20 cm H_2O)
Max. PS:_20_cm H_2O (0–27 cm H_2O)
☐ Settings to be determined via Learn Targets

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iVAPS Therapy Titration Protocol

Initial iVAPS settings:

- Set Patient Height (eg, 70 inches for 5'10")
- Set Target Pt Rate equivalent to patient's spontaneous respiratory rate (eg, 18 bpm)
- Set Target Va such that Vt is equal to 6ml/kg IBW
- EPAP = 5 cm H_2O
- Min PS = 4 cm H_2O
- Max PS = 20 cm H_2O

↓

Evaluate and titrate:

- Based on Target Pt Rate, Target Va, Vt, SpO_2 and CO_2 compared to baseline

↓

For obstructive apneas:

- Increase EPAP by ≥ 1 cm H_2O every ≥ 5 min to eliminate obstructive apneas, hypopneas, snoring and flow limitation

↓

For SpO_2 < 90% with all respiratory events eliminated:

- Increase Target Va by 0.3 every ≥ 5 min until desaturations are resolved

↓

Evaluate if Target Pt Rate is adequate:

- If central events persist, increase Target Pt Rate by 1–2 BPM every 20 min as needed

Indications for iVAPS therapy

- Neuromuscular/restrictive disorders
- COPD
- Obesity hypoventilation

Once a patient is fitted with an appropriate mask, select the appropriate mask setting.

VPAP Adapt Sample Prescription

RESMED

CPAP Therapy

☐ S9 Elite™

☐ Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR™: ☐1 ☐2 ☐3

APAP Therapy

☐ S9 AutoSet™ DEFAULTS

☐ AutoSet Mode
☐ Default Mode Settings
Min. Pressure:_____cm H_2O (4 cm H_2O) 4
Max. Pressure:_____cm H_2O (20 cm H_2O) 20
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

☐ CPAP Mode
Pressure:_____cm H_2O (4–20 cm H_2O)
Ramp Time:_____min(s) (OFF–45 min.)
EPR: ☐1 ☐2 ☐3

Bilevel Therapy

☐ S9 VPAP™ Auto DEFAULTS

☐ VAuto Mode
☐ Default Mode Settings
Max. IPAP:_____cm H_2O (4–25 cm H_2O) 25
Min. EPAP:_____cm H_2O (4 cm H_2O–IPAP) 4
PS:_____cm H_2O (0–10 cm H_2O) 4
Ramp Time:_____min(s) (OFF–45 min.)

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

☐ S9 VPAP S

☐ Spont Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O–IPAP)
Ramp Time:_____min(s) (OFF–45 min.)
☐ EasyBreathe ON

Bilevel with Backup Rate Therapy

☒ S9 VPAP Adapt DEFAULTS

☐ ASV Mode
☐ Default Mode Settings
EPAP:_____cm H_2O (4–15 cm H_2O) 5
Min. PS:_____cm H_2O (0–6 cm H_2O) 3
Max. PS:_____cm H_2O (5–20 cm H_2O) 15
Ramp Time:_____min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☒ ASV Auto Mode
☒ Default Mode Settings
Min. EPAP: 4 cm H_2O (4–15 cm H_2O) 4
Max. EPAP: 15 cm H_2O (4–15 cm H_2O) 15
Min. PS: 3 cm H_2O (0–6 cm H_2O) 3
Max. PS: 15 cm H_2O (5–20 cm H_2O) 15
Ramp Time: OFF min(s) (OFF–45 min.)
Backup Rate: automatic (15 BPM)

☐ S9 VPAP ST

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–25 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–30 BPM)

☐ S9 VPAP ST-A

__Note:__ Ensure Ti Max, Ti Min, Rise Time, Trigger and Cycle are set appropriately to maintain patient-device synchrony

☐ Spont/Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)

☐ PAC Mode ☐ Timed Mode
IPAP:_____cm H_2O (4–30 cm H_2O)
EPAP:_____cm H_2O (3–25 cm H_2O)
Rate:_____BPM (5–50 BPM)
Ti:_____sec. (0.1–4 sec.)

☐ iVAPS Mode
Height:_____in. (44–100 in.)
Target Patient Rate:_____BPM (8–30 BPM)
Target Va:_____L/min. (1–30 L/min.)
Vt (Tidal Volume)_____(mL)
Vt/kg_____(mL/kg)
EPAP:_____cm H_2O (3–25 cm H_2O)
Min. PS:_____cm H_2O (0–20 cm H_2O)
Max. PS:_____cm H_2O (0–27 cm H_2O)
☐ Settings to be determined via Learn Targets

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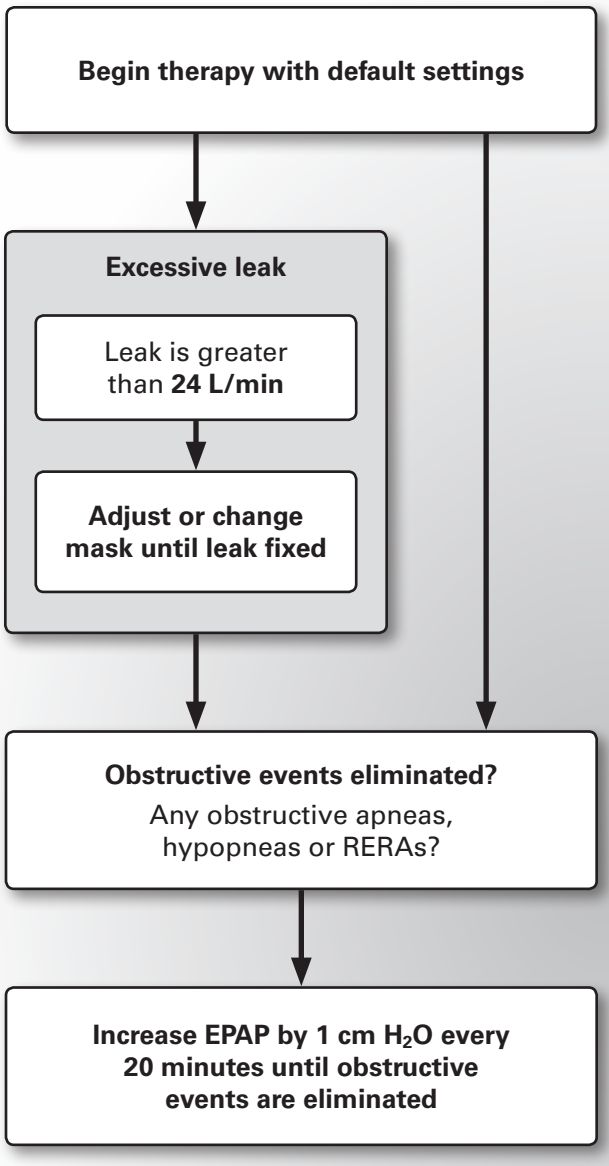
VPAP Adapt Script

VPAP Adapt Therapy Titration Protocol


Begin therapy with default settings
Excessive leak
Leak is greater than **24 L/min**
Adjust or change mask until leak fixed
Obstructive events eliminated?
Any obstructive apneas, hypopneas or RERAs?
Increase EPAP by 1 cm H_2O every 20 minutes until obstructive events are eliminated

Indications for ASV therapy

- Periodic breathing, both normocapnic and hypocapnic
- Other forms of central and concomitant obstructive events[1] (mixed sleep apnea)
- Complex sleep apnea (CompSA)[2]

The guidelines below can help to set up and treat patients with central breathing disorders using the standard ASV mode in ResMed's adaptive servo-ventilation (ASV) devices. This guidance is intended for in-lab titration and should not supercede direction by a physician.

For more details on therapy settings and adjustments, please refer to the Clinical Guide for the specific therapy device.

ASV default settings

Only three therapy parameters to set

EPAP	5 cm H_2O
Min PS	3 cm H_2O
Max PS	15 cm H_2O
Ramp	OFF

ASVAuto default settings

Only four therapy parameters to set

Min EPAP	4 cm H_2O
Max EPAP	15 cm H_2O
Min PS	3 cm H_2O
Max PS	15 cm H_2O
Ramp	OFF

1 Allam JS et al. Efficacy of adaptive servo-ventilation in treatment of complex and central sleep apnea syndromes. *Chest* 2007; 132(6): p. 1839-46

2 Morgenthaler T I et al. Adaptive servo-ventilation versus noninvasive positive pressure ventilation for central, mixed, and complex sleep apnea syndromes. *Sleep* 2007; 30(4): p. 468-75

Notes

Reimbursement

Notes

S9 VPAP Adapt Reimbursement Coding

MD – Primary care physician

ICD-9 Codes

Sleep-related breathing disorders, hypersomnias, circadian rhythm sleep disorders, parasomnias, sleep-related movement disorders (a listing of ICD-9 codes related to sleep disorders can be found in the ResMed Reimbursement Manual)
EXAMPLE: 780.54 Hypersomnia, unspecified

* It is important to note that Medicare will not recognize all codes as medically necessary for sleep disorder testing. Medicare most commonly accepts diagnoses of sleep-related breathing disorders, narcolepsy, parasomnias and impotence.

MD – sleep specialist

ICD-9 Codes

327.21 Primary CSA*

327.22 CSA due to high altitude periodic breathing

327.26 Sleep-related hypoventilation/hypoxemia in conditions classifiable elsewhere (requires underlying diagnosis code)

327.27 CSA in conditions classified elsewhere (requires underlying diagnosis code)

786.04 CSA due to CSR

* Most commonly used for complex sleep apnea patients. These are examples of diagnoses that may be associated with the above mentioned technology. Physicians must determine the appropriate ICD-9 diagnosis based on individual patient needs during the initial exam or through a history and physical.

CPT© Codes

95810 PSG; sleep staging with four or more additional parameters of sleep, attended by a technologist

95811 PSG; sleep staging with four or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist *(94770 carbon dioxide, expired gas determination by infrared analyzer)*

CPT® is a trademark of the American Medical Association

Prescription for S9 VPAP Adapt

HCPCS Code

E0471 Bilevel w/ backup rate

Definitions

Respiratory Insufficiency – Impairment in respiratory function severe enough to prohibit certain activities that the patient might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics and/or gas exchange that are markedly abnormal.

Complex sleep apnea (CompSA) is a form of CSA specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominantly obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to five times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meets the definition of CSA.

CSA is defined as:

(1) An apnea–hypopnea index greater than five; and
(2) Central apneas/hypopneas greater than 50% of the total apneas/hypopneas; and
(3) Central apneas or hypopneas greater than or equal to five times per hour; and
(4) Symptoms of either excessive sleepiness or disrupted sleep.[1]

References

1 Centers for Medicare & Medicaid Services, "LCD for Respiratory Assist Devices (L11493)" U.S. Department of Health and Human Services, http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11493&lcd_version=22&show=all (revision effective date 4/01/2006) *Current Procedural Terminology* ©2005 American Medical Association. All Rights Reserved. *Current Procedural Terminology (CPT)* is copyright 2005 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein Applicable FARS/DFARS restrictions apply to government use.

Medicare Policy for Treatment of OSA

(Effective 2/4/11)

CPAP Qualifications (E0601)

Patient must meet **all** the following criteria to qualify for an E0601 device **(CPAP, such as S9™ Series)**

- ❑ Patient has had a **face-to-face clinical evaluation**[1] by treating physician prior to sleep test. See back for additional information.
- ❑ Patient has had a **Medicare-covered sleep test**[2] that meets either of the following criteria:
  a. AHI/RDI[3] is ≥ 15 events per hour with minimum of 30 events; or,
  b. AHI/RDI is ≥ 5 and ≤ 14 events per hour with minimum of 10 events and documentation of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke. See back for additional information.
- ❑ Diagnosed with OSA (ICD-9 code of 327.23)
- ❑ **Patient and/or caregiver has received instruction** from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

Bilevel Qualifications (E0470)

(Follow for CPAP to bilevel conversion)

Patient must meet **all** the following criteria to qualify for an E0470 device **(bilevel without a backup rate, such as VPAP™ Auto)**

- ❑ Patient is **qualified for E0601 (CPAP)**
- ❑ **Treating physician documented both of the following issues were addressed** prior to changing a patient from an E0601 to an E0470 device due to ineffective therapy:
  a. An appropriate interface has been properly fitted and the beneficiary is using it without difficulty. The properly fitted interface will be used with the E0470 device; and
  b. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy, and lower pressure settings of the E0601 were tried but failed to:
     1. Adequately control the symptoms of OSA; or
     2. Improve sleep quality; or
     3. Reduce the AHI/RDI to acceptable levels.

❑ Yes ❑ No — Has **CPAP been used < 3 months?** (ie, CPAP is tried and found ineffective during the initial 3-month home trial)

If "No," a new initial face-to-face clinical evaluation is required but not a new sleep test. A new 3-month trial would begin for use of the bilevel. See back for additional information.

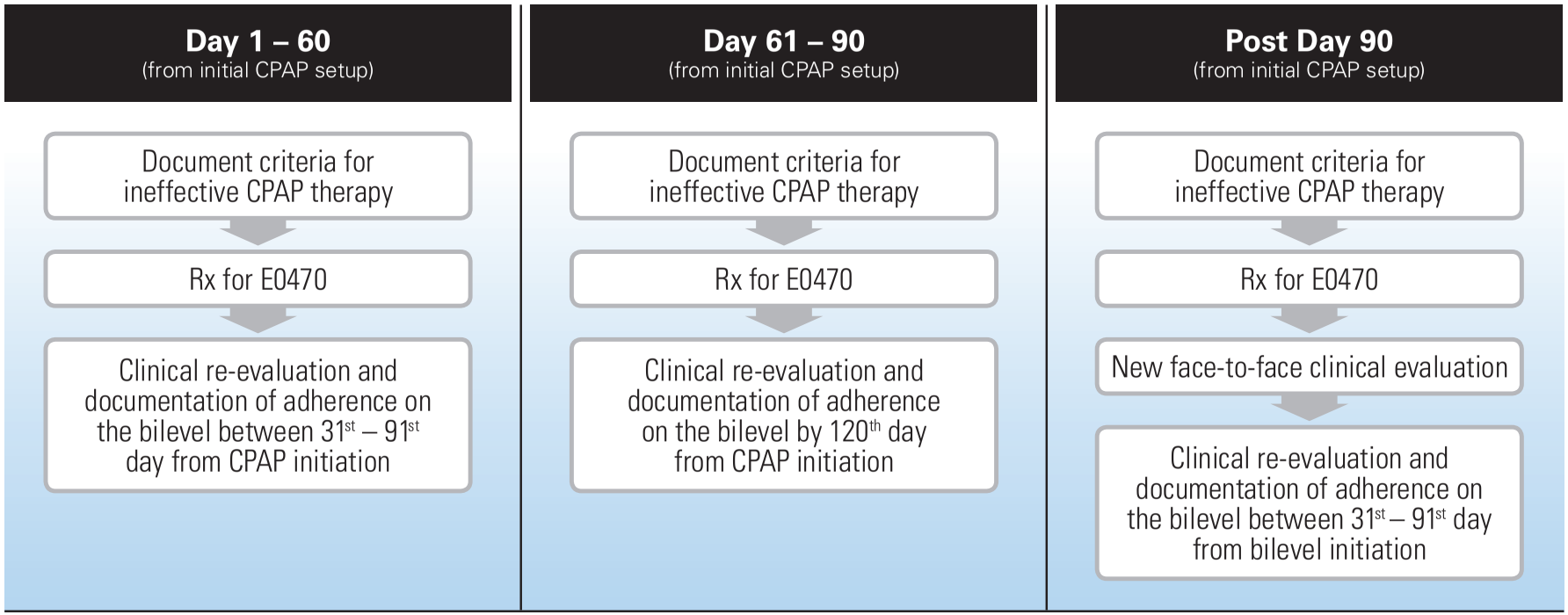
If "Yes," the patient is qualified for an E0470 device (bilevel without a backup rate, such as VPAP Auto). See back for additional information.

Documentation for Continued Coverage[4]

(For continuing to bill months 4-13)

- ❑ Between 31st and 91st day, treating physician has a face-to-face clinical re-evaluation with patient documenting that symptoms of OSA improved.
- ❑ Objective evidence of adherence to use of the PAP device reviewed by treating physician. (Adherence is use of PAP ≥ 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage. Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data.)

Bilevel Conversion Pathways


Day 1 – 60
(from initial CPAP setup)
Document criteria for ineffective CPAP therapy
Rx for E0470
Clinical re-evaluation and documentation of adherence on the bilevel between 31st – 91st day from CPAP initiation
Day 61 – 90
(from initial CPAP setup)
Document criteria for ineffective CPAP therapy
Rx for E0470
Clinical re-evaluation and documentation of adherence on the bilevel by 120th day from CPAP initiation
Post Day 90
(from initial CPAP setup)
Document criteria for ineffective CPAP therapy
Rx for E0470
New face-to-face clinical evaluation
Clinical re-evaluation and documentation of adherence on the bilevel between 31st – 91st day from bilevel initiation

1 **Face-to-face clinical evaluation** may include sleep history and symptoms of OSA, Epworth Sleepiness Scale and physical exam documenting body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation. Some of these elements, in addition to other details, must be documented in patient charts.

2 **Medicare-covered sleep tests** include Type I, Type II, Type III and Type IV (must monitor and record a minimum of three (3) channels). All sleep tests must be interpreted by a physician who is board-certified in sleep medicine by the ABSM, board-certified in sleep medicine by member board of ABMS, trained in an ABMS member board specialty and is awaiting exam, or active staff member of an AASM or The Joint Commission accredited sleep center or lab. (Effective 11/1/08 for Home Sleep Testing and 1/1/10 for Polysomnography)

3 **AHI** is defined as the average number of episodes of apnea and hypopnea per hour of sleep. **RDI** is defined as the average number of apneas plus hypopneas per hour of recording.

4 **If the patient fails the 12-week trial:**
Beneficiaries requalify for a PAP device with both:

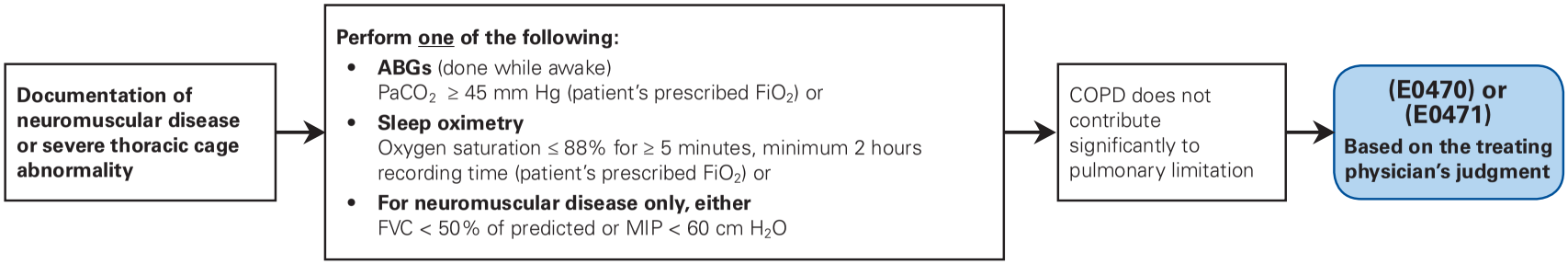
1. Face-to-face clinical re-evaluation by treating physician to determine etiology of failure to respond to PAP therapy; and
2. Repeat sleep test in a facility-based setting (Type 1 study).

Interpreted from: Centers for Medicare & Medicaid Services, "LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea" Jurisdiction A (L11528): http://www.cms.hhs.gov/mcd/. Please note it is the provider's responsibility to verify current requirements and policies with local payors before filing any claims.

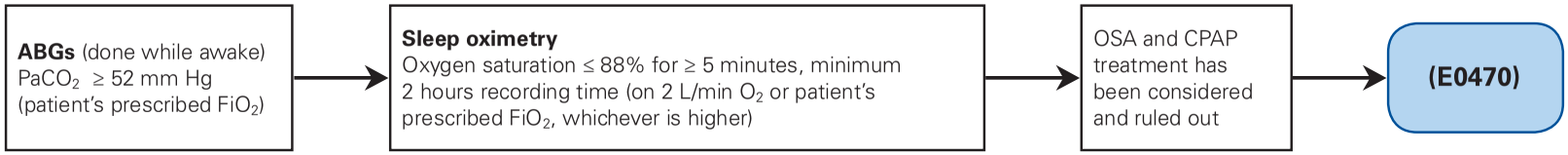
Respiratory Assist Device (RAD) Qualifying Guidelines

CMS guidelines February 2011

I. Restrictive Thoracic Disorders


Documentation of neuromuscular disease or severe thoracic cage abnormality
Perform one of the following:
• ABGs (done while awake) PaCO2 ≥ 45 mm Hg (patient's prescribed FiO2) or
• Sleep oximetry Oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time (patient's prescribed FiO2) or
• For neuromuscular disease only, either FVC < 50% of predicted or MIP < 60 cm H2O
COPD does not contribute significantly to pulmonary limitation
(E0470) or (E0471)
Based on the treating physician's judgment

II. COPD


ABGs (done while awake) PaCO2 ≥ 52 mm Hg (patient's prescribed FiO2)
Sleep oximetry Oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time (on 2 L/min O2 or patient's prescribed FiO2, whichever is higher)
OSA and CPAP treatment has been considered and ruled out
(E0470)

For COPD patients to qualify for a RAD with backup rate (E0471):

Situation 1

After period of initial use of an E0470; ABG (done while awake) shows $PaCO_2$ worsens ≥ 7 mm Hg compared to original ABG result (on patient's prescribed FiO_2); PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time, on an E0470, not caused by obstructive upper airway events (ie, AHI < 5).

Situation 2

No sooner than 61 days after initial use of E0470; ABG (done while awake) shows $PaCO_2$ ≥ 52 mm Hg (on patient's prescribed FiO_2); Sleep oximetry on an E0470 demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time (on 2 L/min O_2 or patient's prescribed FiO_2, whichever is higher).

Respiratory Assist Device (RAD) Documentation Requirements for Continued Coverage

Patients on an E0470 or E0471 device must be reevaluated no sooner than 61 days after initiating therapy.

Required Documentation

- Progress of relevant symptoms
- Signed and dated statement by treating physician declaring patient using average 4 hours per 24-hour period and patient benefiting from use

ResMed E0470 and E0471 Devices

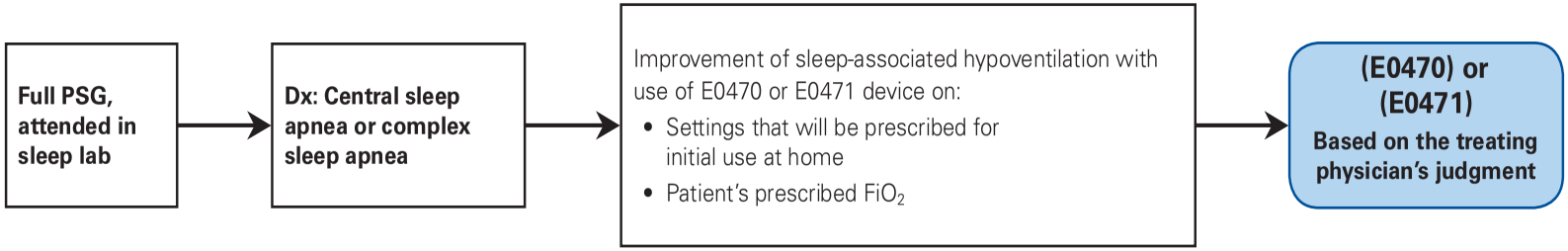
E0470–Bilevel without a backup rate

- VPAP™ Auto
- VPAP S

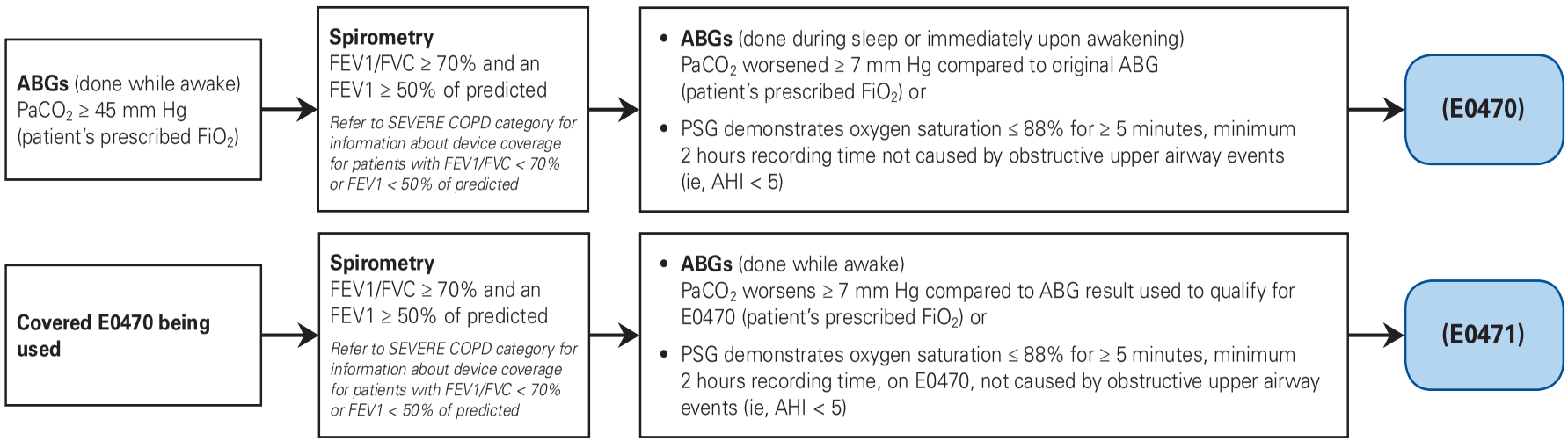
E0471–Bilevel with a backup rate

- VPAP ST
- VPAP Adapt

III. Central Sleep Apnea or Complex Sleep Apnea


Full PSG, attended in sleep lab
Dx: Central sleep apnea or complex sleep apnea
Improvement of sleep-associated hypoventilation with use of E0470 or E0471 device on:
• Settings that will be prescribed for initial use at home
• Patient's prescribed FiO_2
(E0470) or (E0471)
Based on the treating physician's judgment

IV. Hypoventilation


ABGs (done while awake)
$PaCO_2$ ≥ 45 mm Hg
(patient's prescribed FiO_2)
Spirometry
FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted
Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC < 70% or FEV1 < 50% of predicted
• ABGs (done during sleep or immediately upon awakening) $PaCO_2$ worsened ≥ 7 mm Hg compared to original ABG (patient's prescribed FiO_2) or
• PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time not caused by obstructive upper airway events (ie, AHI < 5)
(E0470)
Covered E0470 being used
Spirometry
FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted
Refer to SEVERE COPD category for information about device coverage for patients with FEV1/FVC < 70% or FEV1 < 50% of predicted
• ABGs (done while awake) $PaCO_2$ worsens ≥ 7 mm Hg compared to ABG result used to qualify for E0470 (patient's prescribed FiO_2) or
• PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes, minimum 2 hours recording time, on E0470, not caused by obstructive upper airway events (ie, AHI < 5)
(E0471)

A diagnosis of **central sleep apnea (CSA)** requires all of the following:

1. An apnea hypopnea index > 5
2. Central apneas/hypopneas > 50% of the total apneas/hypopneas
3. Central apneas or hypopneas ≥ 5 times per hour
4. Symptoms of either excessive sleepiness or disrupted sleep

Complex sleep apnea (CompSA) is a form of central apnea

- Identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared
- CompSA patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at ≥ 5 times per hour
- With use of a CPAP or E0470 device, they show a pattern of apneas and hypopneas that meets the definition of CSA

This information is provided as of the date listed, and all coding and reimbursement information is subject to change without notice. It is the provider's responsibility to verify coding and coverage with payors directly. For a full description of the policy go to **www.cms.hhs.gov**. ResMed reimbursement hotline, dial **1-800-424-0737** and select **option 4.**

ResMed

Sleep Lab Titration Guide

Pair S9 VPAP Tx with ResMed's premium masks for successful overnight titrations.

S9™ Series
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